Requirements for Long-Term Care Facilities:
Regulatory Provisions to Promote Efficiency and Transparency
[CMS-3747-P]
Proposed Rule Summary

On July 18, 2019 the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* (84 FR 34737) a proposed rule to modify the Medicare and Medicaid participation requirements for long-term care (LTC) facilities and make related changes in survey, certification and enforcement procedures. In particular, CMS proposes to eliminate or modify rules that it has identified as unnecessary, obsolete, or excessively burdensome.

In addition to substantive changes to regulations, CMS proposes to delay initial implementation of some previously adopted LTC participation requirements that would be modified under this proposed rule until one year after the effective date of the finalization of this proposed rule.

The public comment period for this proposed rule ends on September 16, 2019.

Table of Contents

I. Background

In October 2016 CMS issued a final rule that significantly revised the requirements for participation of LTC facilities in the Medicare and Medicaid programs (81 FR 68688). That rule aimed to recognize advances in service delivery in the LTC facilities and to promote improvements in the quality of care in this setting. In light of the scope of revisions, CMS finalized a phased-in implementation of the new rules and, with respect to rules taking effect in November 2018, provided for an 18-month transition period with a moratorium on civil money penalties and certain other enforcement actions.

Subsequently CMS sought and received public comments regarding areas of potential regulatory burden reduction and cost savings for LTC facilities, including grievance policy requirements (§483.10(j)); the Quality Assurance and Performance Improvement (QAPI) program (§483.75); and removing the requirement that discharge notices be sent to the LTC Ombudsman (§483.15). The comments received along with its own internal review were used to develop this proposed rule.

CMS seeks public comment on additional proposals or modifications to the proposals in this rule that would reduce regulatory burden while preserving quality of care and resident health and safety. Citing its Patients over Paperwork Initiative, CMS is particularly interested in suggestions within its statutory authority to address requirements that make providing quality care difficult or less effective. It says the most useful comments are those that offer supporting data or evidence or that offer amendments or additions to specific regulatory text.

II. Requirements for Participation

The proposed rule would modify a number of the requirements in 42 CFR Part 483 that LTC facilities must meet to participate in Medicare and Medicaid. The proposals are summarized here. **An Appendix to this summary provides the current regulatory text marked up to show the specific changes proposed in this rule.** In a number of places CMS refers readers to interpretive guidelines for LTC facility surveyors for clarity on existing requirements, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.

A. Resident Rights (§483.10)

1. Choice of Physician (§483.10(d)(3)). CMS proposes to modify the current requirement that a facility must ensure that each resident remains informed of the name, specialty, and way of contacting the physician and other primary care professionals responsible for his or her care. Instead, the facility would be required to provide the primary care physician's name and contact information upon admission, with any change of such information or upon the resident's request. CMS believes that this proposal is a clarification and would relieve burden by being specific about facility requirements. **Additional feedback is requested from LTC stakeholders regarding the need for residents to receive contact information for providers responsible for their care outside of their primary care physician, such as a psychiatrist or physical therapist, and how to contact that provider**. Specifically, CMS wants to know how residents

are typically provided with this information and whether it is a standard practice for the primary care physician or facilities to maintain and provide this type of contact information to residents.

2. Grievances (§483.10(j)). The 2016 final rule expanded the grievance process in LTC facilities, including identification of a grievance officer and requirements to ensure prompt resolution of grievances. CMS says that some stakeholders have argued that the required process is overly burdensome, and it proposes changes that it believes will be less prescriptive and burdensome while maintaining facility accountability. **Additional feedback is sought on how to minimize burden while accounting for resident rights and the additional burden on residents and LTC ombudsmen if the changes proposed in this rule are made.**

The proposed changes include distinguishing between resident feedback and a grievance. CMS believes that feedback or complaints that involve general issues can be resolved by staff present when the concern is raised, while grievances are more serious allegations regarding quality of care and require investigations. Under the proposal, CMS says that as part of its grievance policy each facility would determine whether a comment was a grievance or general feedback and would ensure that residents were "fully informed of such determination." CMS emphasizes that under its proposal a resident's right to voice grievance and the facility's responsibility to promptly resolve grievances remains. It expects facilities as a general practice to resolve resident concerns before the grievance process is initiated.

Another proposed change would remove the specific duties set forth for the individual responsible for overseeing the grievance process and would strike the reference to a "Grievance Official." CMS believes this will be less prescriptive and allow facilities flexibility in delegating the responsibilities of the grievance official without impeding a resident's right to voice a grievance. It notes that even under the existing requirements facilities may assign the role of the grievance official to existing staff or assign multiple or additional individuals to assist the grievance official in overseeing the grievance process. Under the proposal, a specific individual would be identified to whom residents would report grievances.

In addition, CMS proposes to modify the language regarding the information to be provided in the written grievance decisions along with the summary of findings and corrective actions to be taken. Specific requirements to provide the dates the grievance was received, and the decision was issued; the investigative steps taken; and whether or not the grievance was confirmed would be eliminated. Instead, the facility would be required to provide <u>any pertinent information</u> including a summary of findings and corrective actions. CMS believes that dates would be routinely provided, and that the revised language focuses on the intent of the requirement.

The final change to the requirements regarding grievances would shorten the time period for which facilities would be required to maintain evidence demonstrating the results of grievances from 3 years from the issuance of the decision to 18 months from that point. CMS states that the 18-month period would reduce recordkeeping burden yet cover the longest possible interval between surveys for a facility and provide enough information for investigations during a survey. **Additional feedback is requested regarding any unintentional consequences from shortened timeframes for record retentions and whether there may be a need to retain records of grievances longer than a survey cycle.**

B. Admission, Transfer, and Discharge Rights (§483.15)

CMS proposes to modify the requirement at §483.15(d)(3) that before a facility transfers or discharges a resident it must send a copy of the notice to a representative of the Office of the State LTC Ombudsman. Under the proposal, this requirement would only apply to involuntary transfers or discharges that are initiated by the facility. It would not apply to emergency transfers to an acute care facility when the patient is expected to return to the LTC facility or to resident-requested transfers. CMS reviews that a facility-initiated involuntary transfer or discharge is (1) one to which the resident objects, (2) did not originate through a verbal or written request by the resident, or (3) is not in alignment with the resident's stated goals and preferences for care. CMS refers readers to the interpretive guidelines (link above) for additional information on this issue. This proposed change is expected to reduce burden by focusing the notification process only on involuntary transfers or discharges. CMS further believes that it would improve resident access to the Ombudsmen program by allowing them to focus directly on inappropriate and involuntary discharges.

C. Quality of Care (§483.25)

Changes to the regulations regarding bed rails at §483.25(n) are proposed. Currently, the facility must attempt to use appropriate alternatives prior to use of a side or bed rail. When a bed rail is used, the facility must meet certain requirements prior to installation. These include requirements that the facility assess the resident for risk of entrapment and also review the risks and benefits of bed rails with the resident (or resident representative) and obtain informed consent.

The proposal would change the requirements regarding risk assessment and informed consent to apply before the bed rail is *used* instead of before it is *installed.* Stakeholders have told CMS that often beds are purchased with the bed rails already installed, which has led to confusion about whether the facility is required to remove rails from beds that are not in use. If removal is required, concerns are raised with how compliance is assessed as well as potential effects on product warranty agreements. CMS believes that the proposed change would clarify the requirements and focus on the appropriate use of bed rails when alternatives are not feasible.

D. Nursing Services (§483.35)

CMS proposes to reduce the minimum length of time under §483.35(g)(4) that LTC facilities must maintain the posted daily nurse staffing data from the greater of 18 months or as required by state law, to the greater of 15 months or the state law requirement. The posted data includes information on the total number and actual hours worked per shift by licensed and unlicensed nursing staff directly responsible for patient care. CMS believes that this proposal provides flexibility and would be sufficient to support any surveyor investigation.

In discussing this proposal CMS notes that some industry stakeholders believe that requirements for payroll-based journal reporting (§483.70(g)) are duplicative of this requirement, but CMS disagrees. The payroll-based journal reporting provisions require facilities to electronically submit to CMS direct care staffing information based on payroll and auditable data. CMS says

that the difference is that the payroll-based journal reporting requirement provides a retrospective look that gives consumers information on typical staffing at a facility on an average day, while the posting requirement at §483.35 provides real time information for residents and families about the amount of staff and which staff are working in the facility for a specific shift.

E. Behavioral Health (§483.40)

Proposed changes to the regulations in this section are made with the goal of improving clarity and eliminating duplication. CMS states that the language regarding sufficiency of staff (§483.40(a)) unnecessarily duplicates language on staff sufficiency in the Nursing Services requirements (§483.35) and proposes to remove it. Also, requirements at §483.40(c) are identical to those at §483.65(a) regarding specialized rehabilitation services, and these are proposed for removal. CMS notes that some stakeholders suggested removing the behavioral health requirements entirely, which it does not propose because it believes that a focus on care for residents with mental disorders or psychosocial adjustment difficulties is needed. Readers are referred to interpretive guidelines released for more information on the behavioral health requirements at §483.40.

F. Pharmacy Services (§483.45)

Changes are proposed to the regulations regarding PRN ("as-needed") orders for psychotropic drugs generally (§483.45(e)(4)), and anti-psychotic drugs specifically (§483.45(e)(5)). Currently for psychotropic drugs, PRN orders are limited to 14 days, with an exception that provides opportunity for the attending physician or prescriber to document in the medical record a rationale for a longer duration to specify the duration. This exception does not apply to PRN orders for anti-psychotic drugs, however. In that case, the PRN order is limited to 14 days and cannot be renewed unless the attending physician or prescriber evaluates the resident for the appropriateness of the medication.

CMS proposes to modify the PRN exception to the 14-day limit and expand it to include all psychotropic drugs, including anti-psychotic drugs. The proposed regulation would provide that the PRN order could be extended beyond the 14-day limit *in accordance with facility policies* if the attending physician or prescriber believes that the extension is appropriate, and they document the rationale in the resident's medical record along with the duration for the PRN order.

Further, the facility would be required to have policies, standards and procedures regarding use of PRN orders for psychotropics that use recognized standards of practice, including the circumstances under which PRN orders can be extended beyond 14 days. The facility's policy would be required to consider its resident population, the individual residents' need for psychotropic drugs, and their access to physicians and other practitioners. In addition, it would have to include standards for how often the attending or prescriber would have to review the PRN order, which could be no less than the frequency of required physician visits (§483.30(c)). Documentation requirements would also apply, including diagnosis, indications for use, nursing documentation describing the circumstances that support the administration of the mediation, and the justification for prolonged use. Finally, the LTC facility's policy would have to include

disclosure requirements that the facility must make to the resident (and his or her representative) when a resident is prescribed an anti-psychotic. The preamble to the proposed rule does not elaborate on this specific proposed requirement.

These proposals are made based on feedback CMS received leading it to conclude that the current requirements could result in negative impacts on residents from interruptions in care. CMS received comments concerned that the 14-day limit results in prescribers avoiding use of PRN orders and instead writing routine orders that result in residents receiving more of the drug more often than if it were given only as needed. The requirement for in-person evaluations of patients receiving a PRN order for anti-psychotics was considered unrealistic considering the access to care issues in some settings. In addition, comments asserted that limited guidance for surveyors had caused improper rejections and citations for appropriate pharma-therapeutic decisions, which were detrimental to patients and caused administrative burden for providers.

In considering these comments, CMS concludes that having the same requirements for all psychotropic drugs would simplify the survey process and reduce improper deficiency citations. and remove obstacles for mental health professionals to provide quality care to residents. It also believes the proposals will increase flexibility for facilities and providers in treating patients without excessive administrative burden.

Regarding the proposal to require that the facility's policies, standards and procedures use recognized standards of practice, CMS acknowledges that it has not indicated any specific standards. It expects that experts in medicine and pharmacology would develop national standards that could be used in LTC facilities, and that the mental health professionals that practice in the facility along with the medical director and director of nursing would have significant input into a facility's policies. **CMS is interested in comments on standards that could be used to satisfy this requirement.**

CMS also discusses its concern about the potential misuse of psychotropic drugs, especially anti-psychotics. A 2018 Human Rights Watch report is cited, which concluded that anti-psychotic medications are being used as chemical restraints and for the convenience of staff in LTC facilities. CMS also notes a joint statement released by numerous organizations urging clinicians to be mindful of labeling patients with other diagnoses (e.g., schizophrenia) to justify the use of certain medications or treatments.[1]

Comments are solicited on whether the proposed changes to PRN orders for psychotropic drugs provide sufficient protection for residents. Feedback on whether the current policy should be retained is welcomed, and additional information is sought regarding:

- the impact that the current PRN policy for anti-psychotic drugs has on resident care in LTC facilities, such as access to health care professionals, timing of a resident receiving

[11] See Human Rights Watch. February 2018. *They Want Docile—How Nursing Homes in the United States Overmedicate People with Dementia*. https://www.hrw.org/report/2018/02/05/they-want-docile/how-nursing-homes-united-states-overmedicate-people-dementia and "Joint Summary Statement – Diagnosing Schizophrenia in Skilled Nursing Centers," press release, The Society for Post-Acute and Long-Term Care Medicine, February 21, 2017, https://paltc.org/newsroom/joint-summary-statement-diagnosing-schizophrenia-skilled-nursing-centers.

necessary medications, interruptions in resident care, or any other consequences of retaining the current PRN policy for anti-psychotic drugs;

- alternative policy options that CMS could take to address concerns surrounding PRN orders of psychotropic drugs and an explanation of how such alternatives would provide resident protections, without limiting a resident's access to necessary medications;
- whether the 14-day limitation on PRN orders is reasonable, especially in light of the proposal to allow a prescriber to extend the order by writing his or her rationale in the resident's medical record and indicating the duration of the order. If not reasonable, CMS asks that commenters provide recommendations to improve the proposed requirements;
- whether there should be a specific requirement for evaluating residents before renewing a PRN order for an anti-psychotic drug and if so, at what time intervals and what type of valuation should be required.

G. Food and Nutrition Services (§483.60)

Changes are proposed to the requirements for an LTC facility director of food and nutrition services (§483.60(a)(2)). The October 2016 final rule introduced new standards for this position, and CMS has received feedback from industry stakeholders that the new standards may have led to unnecessary burden and costs on facilities. The burden of requiring experienced staff to receive additional credentials and concerns about workforce shortages were expressed.

The proposed changes would strike the credentials specified in the current requirements under which the director must be a certified dietary manager, certified food service manager, a similarly credentialed individual or one with at least an associate's degree in food service management or hospitality. Instead, the proposed rule would require that the director of food and nutrition services have two or more years experience as director of food and nutrition services in a nursing facility setting or have completed a course of study in food safety and management that includes topics integral to managing dietary operations such as foodborne illness, sanitation procedures, and food purchasing/receiving. The existing requirement that the director receive frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional would be retained.

H. Administration (§483.70)

Based on comments from stakeholders about the burden on LTC facilities from the existing requirements at §483.70(e) for a facility assessment, CMS proposes changes. The current requirements require the facility to conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually and whenever there are changes involving a substantial modification to any part of the assessment.

CMS says its proposed changes would remove unnecessary requirements and clarify that data collected under the facility assessment requirement could also be used to inform policies and procedures for other LTC requirements. Specifically, the frequency of assessment review and updating would change from annual to biennial; the requirement for inclusion of a facility-based

and community-based risk assessment utilizing an all-hazards approach would be eliminated; and the regulatory text would specify that information from the facility assessment requirement must be used to inform policies and procedures in accordance with the requirements for Nursing Services (§483.35), Behavioral Health (§483.40), Food and Nutrition Services (§483.60) and the Quality Assurance and Performance Improvement (§483.75). The QAPI requirements include program feedback, data systems and monitoring, and CMS believes that data collected under the QAPI requirement could be used to meet some of the facility assessment requirements and vice versa. Other requirements detailing the required content of the facility assessment would remain unchanged.

Regarding the proposal to reduce the minimum frequency of facility assessments to every 2 years, CMS notes that more frequent assessments may continue, and references the requirements for QAPI plan assessments. It believes the change would reduce burden and improve administrative flexibility, especially for rural providers with limited resources. CMS states that in facilities with a high staff turnover, assessments should take place as frequently as necessary and the issue should be addressed in the QAPI plan, which must be presented at the annual recertification survey and upon request by CMS or during any other survey. CMS believes that the combined LTC requirements (for example, emergency preparedness; QAPI; and facility assessment) would help to optimize health and safety, while reducing burden. A facility would review and update its assessment as necessary, and, at a minimum, every 2 years.

With respect to the proposed elimination of the required risk assessment as part of the facility assessment, CMS believes this unnecessarily duplicates the more detailed requirement under §483.73(a) to develop and maintain an emergency preparedness plan, which must be based on a documented facility-based and community-based risk assessment, utilizing an all-hazards approach.

I. Quality Assurance and Performance Improvement (§483.75)

CMS proposes modifications to the QAPI requirements after considering comments in which some industry stakeholders that they are inflexible and too detailed, which makes it difficult for facilities to identify priorities for improvement. Resident advocates stated the QAPI process is new in the LTC setting (it was added by the Affordable Care Act) and the specificity is needed to ensure consistency and efficacy of the QAPI process.

The proposed changes would eliminate the detailed requirements currently found in subparagraphs under §483.75(b) regarding program design and scope; §483.75(c) regarding program feedback, data systems, and monitoring; and §483.75(d) for program systematic analysis and systemic action. In these paragraphs only the following broad requirements would be maintained:

> (b) *Program design and scope.* A facility must design its QAPI program to be ongoing, comprehensive, and capable of addressing the full range of care and services provided by the facility.
> (c) *Program feedback, data systems and monitoring.* A facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring, including adverse event monitoring.

(d) *Program systematic analysis and systemic action.* 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.

Other requirements in this subsection would remain unchanged, including those at §483.75(a)(1) through (4) involving facility maintenance of documentation and evidence of a QAPI program. CMS believes that these requirements are necessary for a facility to demonstrate compliance and to ensure that its QAPI program is ongoing, and it expects that any review of QAPI documents would occur at the end of a facility survey, after a completed investigation into all other requirements. Readers are referred to the interpretive guidelines (link above) for a discussion of disclosure of information and good faith attempts.

CMS believes that striking the detailed requirements would recognize diversity among LTC facilities and reduce burden on them by providing more flexibility in tailoring QAPI programs to meet specific facility needs. In addition, CMS states that the proposed changes are consistent with QAPI requirements for hospitals and other major types of Medicare and Medicaid inpatient providers.

J. Infection Control (§483.80)

CMS cites the clinical literature in discussing the importance of infection control in the LTC facilities, and affirms that the current infection control requirements should be retained, with one change regarding individuals designated as infection preventionists (IPs). The current requirements for an IP specify that the individual work at least part time at the facility. The proposal would change this to state that the individual must have sufficient time at the facility to achieve the objectives set forth in the facility's infection prevention and control program. CMS believes that this change is needed because the term "part time" could be interpreted in various ways, but also recognizes that facilities could vary in how they interpret the proposed requirement. **Comments are sought on how it should be determined that the IP has sufficient time to ensure that he or she can achieve the objectives of the facility's infection prevention and control plan. CMS asks that commenters please be specific.**

K. Compliance and Ethics Program (§483.85)

CMS proposes to eliminate and modify some of the existing requirements for a facility's compliance and ethics program, generally eliminating text that is not required by statute. It says that the skilled nursing facility (SNF) and nursing facility (NF) Conditions of Participation would provide the appropriate safety and quality standards to support the remaining compliance and ethics requirements. CMS refers readers to compliance program guidance from the Office of the Inspector General from March 16, 2000 (65 FR 14289) and September 30, 2008 (73 FR 56832).

The specific proposed changes follow:

- The requirement in §483.85(c)(1) that the written compliance and ethics standards, policies and procedures for all LTC facilities designate a compliance and ethics program

contact person to whom individuals may report suspected violations would be removed.[2] CMS says that facilities must have a process to accomplish this but does not want to "dictate who they should hire to comply with the requirement."

- The requirement at §483.85(c)(1) requiring all facilities to have disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff, contract employees and volunteers (consistent with volunteers' expected roles) would also be removed. This specific change is not discussed in the preamble. Throughout its discussion of this subsection CMS emphasizes that facilities would be held accountable for effective operation of its compliance and ethics program. The existing requirements that facilities take reasonable compliance steps (including monitoring and detection of violations by staff, contract employees and volunteers) and disciplinary actions would be retained.
- Although the proposed rule would retain the requirement that an LTC facility have an alternate method of reporting suspected violations anonymously (in a new §483.85(c)(9)), the current text appearing in §483.85(c)(1) would be modified to eliminate the phrase "without fear of retribution." This change is not specifically discussed in the preamble to the proposed rule.
- The list of reasonable steps in §483.85(c)(6) for LTC facilities to achieve compliance with the program's standards, policies and procedures is modified to remove "having a process for ensuring the integrity of any reported data." This specific change is not discussed in the preamble.
- The requirement at §483.85(d)(1) for operating organizations with five or more facilities to have a mandatory annual training program would be replaced with a requirement that the facility have "a more formal program" that includes written policies defining the standards and procedures for employees to follow.
- The requirements at §483.85(d)(2) and (3) for operating organizations with five or more facilities to name a dedicated compliance officer and designated compliance liaisons would be removed and replaced with a requirement that these facilities have a compliance and ethics program that is "appropriate for the complexity of the operating organizations and its facilities." CMS would retain the current requirement for all facilities (§483.85(c)(2)) that a specific individual within the high-level personnel of the operating organization have overall responsibility to oversee compliance, although language would be struck that identifies the organization's CEO, board members and directors of operating divisions as examples of who might be given this responsibility. CMS says that this language is prescriptive and that facilities would be held responsible for the effective operation of its programs.
- The Program Review requirement at §483.85(e) would be changed from an annual review to a periodic review. Note that the Executive Summary of the proposed rule and the regulatory impact analysis state that the change would be from annual to biennial review, but this statement is not supported by the proposed regulatory text or by the

[2] In the preamble, CMS later says that the "compliance and ethics program contact in the compliance and ethics program would be required to ensure consistent enforcement of the operating organizations standards, policies, and procedures…" The regulatory text would retain the current requirement for consistent enforcement which does not name a responsible individual; presumably this is the individual(s) within high-level personnel responsible for oversight of the compliance and ethics program.

discussion in the part of the preamble detailing the proposed changes. In both these places CMS is clear that the proposal is for periodic review.

L. Physical Environment (§483.90)

Life Safety Code. CMS discusses changes to the Life Safety Code published in 2016 (81 FR 26871) and its subsequent updating to a newer edition of the National Fire Prevention Association 101A Fire Safety Equivalent System (FSES). The newer edition had changes in scoring that resulted in some LTC facilities no longer being able to achieve a passing score, an outcome that CMS had not anticipated. An estimated 50 facilities are in this circumstance. The issue involves facilities of 3 or more stories in height that were previously built with wood frame or unprotected steel construction with less than 2 hours of fire rated protection. Although fully sprinklered under the new edition these facilities would need to improve to a construction type that is at least 2 hours of fire rated protection, a change that CMS notes is extremely burdensome at a typical cost of $4.75 million per facility and associated service disruptions. CMS believes that this requirement would result in some permanent facility closures and access to care problems. Facilities have been given the opportunity to apply for a waiver of this requirement for up to 5 years while CMS pursues a long-term solution.

In this rule, CMS proposes to allow LTC facilities that were Medicare- or Medicaid-certified before July 5, 2016 that have previously met the FSES requirements to continue to do so. The following table of mandatory scoring values would be added to §483.90(a)(1)(iii).

Table 1. Proposed Mandatory Values—Nursing Homes

	Containment (Sa)		Extinguishment (Sb)		People Movement (Sc)	
Zone Location	New	Exist.	New	Exist.	New	Exist.
1st story	11	5	**15(12)***	4	**8(5)***	1
2nd or 3rd story **	15	9	**17(14)***	6	**10(7)***	3
4th story or higher	18	9	**19(16)***	6	**11(8)***	3

* Use ( ) in zones that do not contain patient sleeping rooms [** appears in the table but the regulatory text does not include an explanatory footnote.]

Resident Rooms and Bathrooms. Under the provision adopted in the 2016 final rule, resident rooms in LTC facilities must accommodate no more than four residents, except that for facilities that receive state and local approval of construction or reconstruction plans or are newly certified after November 28, 2010, bedrooms must accommodate no more than two residents. With respect to bathrooms, for facilities that receive state and local approval of construction or are newly certified after that date, each resident room must have its own bathroom including at least a commode and sink.

CMS proposes to modify the requirements for resident rooms and bathrooms by applying the 2-resident per room and individual bathroom requirements only to facilities that are newly constructed and newly certified facilities *that have never previously been a LTC facility*. The proposal is made in response to stakeholder concerns about the burdens and unintended consequences of the current requirement, including disincentives to build, remodel, upgrade or

purchase LTC facilities. CMS believes the proposed changes would eliminate any unintended disincentives to purchase or upgrade existing facilities, while continuing to ensure that new facilities are properly equipped.

On the other hand, CMS notes that purchasing or updating a facility provides an opportunity to update rooms and bathrooms to address infection risks and quality of life concerns. **Comments are sought on whether it would be appropriate to sunset the proposed exception for buildings that previously were LTC facilities. If so, CMS asks what a reasonable time frame would be for sunsetting the proposed provision in order to balance the resident needs for privacy and quality of life, infection prevention and the desire to maintain access to facilities and avoid the unintended consequences of the current requirement.**

M. Technical Corrections

A number of technical changes are proposed to the regulatory text in §483.15, §483.85, §483.90, and §410.32.

III. Survey, Certification, and Enforcement Procedures

Changes are proposed to certain survey, certification and enforcement procedures under 42 CFR Part 488 involving facility compliance with the LTC requirements.

A. Informal Dispute Resolution (IDR) (§483.331) and Independent IDR (§488.431)

LTC facilities that have been certified under a state or federal survey as noncompliant have an opportunity to dispute cited deficiencies through an IDR process under §483.331. IDR is provided by the state when the deficiencies were cited under a survey conducted by the state. In the case of a disputed civil money penalty (CMP) imposed by CMS, the facility may request an Independent IDR under §488.431.

Changes are proposed with respect to the timing of the IDR process; the timing of when survey information is uploaded for use in the Nursing Home Compare quality ratings; the process for written notification of Independent IDR decisions; and the qualifications of umbrella state agencies for conducting Independent IDR.

60-Day Time Frame for Completion of IDR. There is currently no specification for how long the IDR process should take to be completed, while the Independent IDR process (§488.431(a)) must be completed within 60 days of the facility's request if the request is made timely. In this rule, CMS proposes to specify that the IDR process would be completed within 60 days of the facility's request if the request is made timely. It believes that using the same timeframe would reduce confusion and ensure consistency between the IDR and Independent IDR processes. CMS notes that under the current requirements for Independent IDR, facilities are still required to pay the disputed CMP. These funds are held in an escrow account until a final administrative decision is made. CMS states that the proposed 60-day time frame for completion of the IDR process would potentially reduce burden on facilities who would have the CMP payments returned to them sooner when they are successful in their appeal.

State Upload of Survey Results into CASPER system. CMS proposes that to add specific instructions to states in §488.331(b)(2) to stop states from uploading survey results into the Certification and Survey Provider Enhanced Reporting (CASPER) system before the resolution of the IDR or Independent IDR processes. The uploaded information is used to calculate a facility's 5-star quality rating on the Nursing Home Compare website, and CMS states that this proposal would reduce burden on providers by ensuring that Nursing Home Compare contains accurate survey information that includes any post-survey review through the IDR or Independent IDR process. It also expects to reduce burden on states by minimizing the amount of corrections and changes to data that would be needed if information were uploaded prematurely.

Written Notification of Independent IDR Decision. A new requirement is proposed at §488.331(a)(2) under which a facility must receive written notification of the results of the Independent IDR, including the rationale for the final decision. Currently, guidance requires that the facility receive the recommendation of the Independent IDR entity. Under the proposal, the rationale for the final decision would be provided by CMS or the state depending on which made the final determination and would account for situations in which the IDR entity's recommendation is not accepted as the final decision. CMS believes this would reduce facility burden associated with trying to understand the process for requesting an explanation of the final decision.

Conduct of Independent IDR. Currently a component of an umbrella state agency may conduct an Independent IDR process, if the component is separate from the state survey agency. CMS proposes to add clarifying language that the component must have a specific understanding of Medicare and Medicaid program requirements. This is a current requirement for an independent entity, it is not specified in the example given for a separate component of an umbrella state agency.

B. Civil Money Penalties (§488.436)

A facility may elect (in writing) to waive the right to a hearing within 60 days of receiving a notice imposing a CMP, in which case the CMP is reduced by 35 percent. CMS reports that in 2016, 81 percent of LTC facilities submitted a written waiver of the hearing and another 15 percent did not submit a waiver but also did not contest the penalty and its basis – only 4 percent took advantage of the full hearing process.

Because so few facilities engage in a hearing when a CMP is imposed, CMS proposes to replace the requirements for filing a written waiver. Instead, a facility would be deemed to have waived its rights to a hearing when CMS has not received a timely request for a hearing. The 35 percent reduction in the CMP would apply. CMS notes that most of the 81 percent of facilities that submit a request for a waiver of hearing do so toward the end of the 60-day period for filing the request (to delay the due date of the CMP). As a result, CMS believes that the proposed default process would meet the needs of facilities facing a CMP. It believes that other circumstances could be addressed under §488.444, which provides authority for CMS to settle CMP cases any time prior to a final administrative decision for Medicare-only SNFs, state-operated facilities, or other facilities for which CMS' enforcement action prevails, in accordance with the rules under

§488.330. (The preamble incorrectly references §488.30 here.) **CMS seeks comments addressing any potential circumstances under which a facility's needs could best be met or only met through use of an express, written waiver.**

C. Implementation Delay of Certain Phase 3 LTC Facility Participation Requirements

The CoPs finalized in November 2016 were implemented in phases with Phases 1 and 2 implemented in November 2016 and November 2017, respectively, and the additional requirements of Phase 3 scheduled to be implemented in November 2019. The proposed rule would modify the Phase 3 provisions involving designation and training of the infection preventionist (§483.80), QAPI (§483.85), and the compliance and ethics program (§483.85).

In order to avoid unnecessary work and confusion associated with implementing provisions that would be changed under this proposed rule, CMS proposes to delay implementation of certain of the Phase 3 regulatory provisions that would be affected under this proposed rule until one year after the finalization of this rule. The specific provisions proposed for delay are shown in the modified version of proposed rule Table 2 shown below. An Appendix to this summary shows the existing regulatory text that would be modified by this proposed rule. Some of the provisions listed below involving QAPI and the Compliance and Ethics Program requirements are not shown in the Appendix because no changes to the specific regulatory text are proposed; CMS is proposing with one exception to delay implementation of all the QAPI provisions (§483.75) and all the compliance and Ethics Program provisions in §483.85.

CMS proposes not to delay the implementation of the infection preventionist provisions because the proposed change is related to the amount of time the preventionist is required to spend onsite, which would not interfere with the implementation of the provision as scheduled.

Phase 3 Regulatory Provisions Proposed for Delayed Implementation	
Current CFR Citation	**Subject**
483.75(a)(1), (4)	Quality Assurance and Performance Improvement (QAPI)
483.75 (b)(1)-(4)	QAPI Program Design and Scope
483.75 (c)(1)-(4)	QAPI Program Feedback, Data Systems, and Monitoring
483.75 (d)(1)-(2)	Program Systematic Analysis and Systematic Action
483.75 (e)(1)-(3)	Program Activities
483.75 (f)(1)-(6)	Governance and Leadership
483.75 (g)(2)(iii)	Quality Assessment and Assurance
483.85(a)-(e)	Compliance and Ethics Program
483.95(d)	QAPI Training
483.95(f)(1)(2)	Compliance and Ethics Training
Other Phase 3 Regulatory Provisions Affected by this Proposed Rule but NOT Proposed for Delayed Implementation	
483.75(g)(1)(iv)	QAPI (participation of infection preventionist)
483.80(b)(1)-(4)	Infection Preventionist
483.80 (c)	Infection Preventionist Qualifications/Specialized Training

IV. Collection of Information Requirements and Regulatory Impact Analysis

CMS estimates that the overall impact of the changes in the proposed rule during the first full year of implementation would total $644 million in savings, almost exclusively by reducing costs to the 15,639 LTC facilities that participate in Medicare and Medicaid. The estimates are summarized in Table 4 of the proposed rule, which is reproduced in part here. (Only provisions with associated savings estimates are shown in this summary table.) **CMS welcomes comments on the burden assumptions and estimates of likely savings.**

Regulatory Provisions	Annual Information Collection Savings	Annual Other Savings	Total Annual Savings
A. Requirements for Participation			
Grievances (§483.10(j))	NA	$78,069,888	$78,069,888
Admission, Transfer, and Discharge Rights (§483.15)	$1,473,047	NA	$1,473,047
Food and Nutrition Services (§483.60)	NA	$19,142,136	$19,142,136
Facility Assessment (§483.70(e))	$13,809,237	NA	$13,809,237
QAPI (§483.75)	$39,222,612	NA	$39,222,612
Compliance and Ethics Program (§483.85)	$4,907,069	$109,909,488	$114,816,557
Life Safety Code (§483.90(a))	NA	$48,000,000	$48,000,000
Resident Rooms and Bathrooms (§483.90(e),(f))	NA	$328,000,000	$328,000,000
B. Survey, Certification, and Enforcement Procedures			
CMP waivers (§488.436)	NA	$1,233,112	$1,233,112
Totals	**$59,411,96**	**$584,354,624**	**$643,766,589**

In the Accounting Statement included as Table 5 of the proposed rule, CMS estimates 10-year annual cost reductions at $570 million or $580 million, depending on whether a 3 percent or 7 percent discount rate is used in the analysis. These totals are less than the first-year savings estimates above primarily because the savings associated with the proposed changes to the Life Safety Code would only be achieved during the first 5 years, while the statement provides a 10-year annualized estimate.

Information Collection Savings

By reducing information collection, recordkeeping and disclosure requirements, CMS estimates that the proposed rule would generate $59.4 million in first-year savings across all LTC facilities.

- Savings of almost $1.5 million[3] would result from the proposal to limit the required notification of the state LTC Ombudsman to involuntary discharges and transfers only.
- The proposal to require the facility-wide assessment biennially instead of annually is estimated to save $13.8 million.

[3] This figure appears in the Collection of Information section of the proposed rule and in proposed rule Table 4. In the Regulatory Impact section, CMS refers to savings from this provision as totaling $1.148 million.

- Acknowledging that proposed changes to QAPI would give facilities more flexibility in implementing this program and are difficult to predict, CMS assumes the cost of the program would be reduced by half, with estimated savings of $39.2 million across all facilities.
- A total of $4.9 million in savings is estimated to come from proposals to modify the Compliance and Ethics Program requirements; $2 million from eliminating the annual training requirement and $2.9 million from changing the program review from annual to biennial. (As noted above the proposed regulatory text and preamble discussion call for a periodic review, although the Executive Summary of this proposed rule also state the proposal is for biennial review.)

Other Savings

CMS estimates that other savings would also result from the proposed rule, totaling $584.4 million for the first full year of implementation.

- Changing the requirements for LTC facility grievance policies, in particular eliminating the specific duties required of the individual responsible for overseeing the grievance process, is estimated to cut in half the costs to facilities of carrying out the grievance policy requirements, with savings estimated at $78.1 million. **CMS specifically requests comments on its assumption that the proposal would result in savings of 5 percent of a social worker FTE at $48 per hour.**
- Proposed revisions to the qualifications required for the director of food and nutrition services is estimated to total $19.1 million.
- Changes proposed for the Compliance and Ethics Program requirements, specifically elimination of the requirements for a compliance officer and compliance liaison are estimated to save $109.9 million. Together with the estimated $4.9 million[4] in collection of information savings the changes to these program requirements would total $114.8 million.
- The proposed changes in the Life Safety Code are estimated to total $48 million a year, estimated as the annual savings of $240 million in costs that would be required to replace the 50 facilities that no longer meet the Life Safety Code requirements, spread over five years.
- First-year savings from the proposal to limit application of the bedroom and bathroom requirements to newly constructed facilities and newly certified facilities that have never previously been an LTC facility are estimated to total $328 million.
- Reduced civil money penalties under the proposal to modify the process for a facility to waive a hearing are estimated to total $0.7 million, and CMS estimates the reduced administrative burden on facilities would total $0.4 million, and that the CMS regional offices would save $0.1. Total savings from this proposal would be the sum of these, or $1.2 million.

[4] The $4.9 million figure appears in the Collection of Information section of the proposed rule and in proposed rule Table 4. In the Regulatory Impact section, CMS refers to savings from this provision as totaling $13.7 million and the total savings associated with the Compliance and Ethics Program requirements changes equaling $123.6 million.

Other Impacts

One-time costs totaling $11 million ($680 per facility) are estimated to result from the proposed changes. Even though the proposed changes reduce burden, this estimate reflects the time spent by lawyers, administrators and other staff to read, understand and implement the changes.

CMS did not attempt to estimate the effects of the proposed rule on residents of LTC facilities. It believes that no substantial increases or reductions in the quality of patient care would result. By reducing burden, some facility staff time would be freed up and potentially available for services that benefit residents, but CMS believes these are likely small effects. **Comments that focus on patient care effects are welcomed.**

APPENDIX

Summary Table of Proposed Changes to Regulatory Text

(Proposed new text in italics; proposed removals in ~~strikeout~~)

42 CFR Part 483 – Requirements for States and Long-Term Care Facilities

483.10 Resident rights.

483.10(d)(3) The facility must ~~ensure that each resident remains informed of the name, specialty, and way of contacting the physician and other primary care professionals responsible for his or her care.~~ *provide the primary care physician's name and contact information upon admission, with any change of such information or upon the resident's request.*

483.10(j) Grievances. (1) The resident has the right to voice grievances to the facility or other agency or entity that hears grievances without discrimination or reprisal and without fear of discrimination or reprisal. Such grievances include those with respect to care and treatment which has been furnished as well as that which has not been furnished, the behavior of staff and of other residents; and other concerns regarding their LTC facility stay *that differ from general feedback from residents or their resident representative*.

(2) The resident has the right to and the facility must make prompt efforts by the facility to resolve grievances the resident may have, in accordance with this paragraph *(j)*.

(3) The facility must make information on how to file a grievance or complaint available to the resident.

(4) The facility must establish a grievance policy to ensure the prompt resolution of all grievances regarding the residents' rights contained in this paragraph. Upon request, the provider must give a copy of the grievance policy to the resident. The grievance policy must include:

(i) Notifying resident individually or through postings in prominent locations throughout the facility of the right to file grievances orally (meaning spoken) or in writing; the right to file grievances anonymously; ~~the contact information of the grievance official with whom a grievance can be filed, that is, his or her name, business address (mailing and email) and business phone number;~~ a reasonable expected time frame for completing the review of the grievance; the right to obtain a written decision regarding his or her grievance; and the contact information of independent entities with whom grievances may be filed, that is, the pertinent State agency, Quality Improvement Organization, State Survey Agency and State Long-Term Care Ombudsman program or protection and advocacy system;

(ii) Identifying ~~a Grievance Official~~ *an individual* who is responsible for overseeing the grievance process~~, receiving and tracking grievances through to their conclusion; leading any necessary investigations by the facility; maintaining the confidentiality of all information associated with grievances, for example, the identity of the resident for those grievances submitted anonymously; issuing written grievance decisions to the resident; and coordinating with state and federal agencies as necessary in light of specific allegations~~;

(iii) As necessary, taking immediate action to prevent further potential violations of any resident right while the alleged violation is being investigated;

(iv) Consistent with §483.12(c)(1), immediately reporting all alleged violations involving neglect, abuse, including injuries of unknown source, and/or misappropriation of resident property, by anyone furnishing services on behalf of the provider, to the administrator of the provider; and as required by State law;

(v) Ensuring that all written grievance decisions include ~~the date the grievance was received, a summary statement of the resident's grievance, the steps taken to investigate the grievance,~~ *any pertinent information including but not limited to* a summary of the ~~pertinent~~ findings or conclusions ~~regarding the resident's concern(s), a statement as to whether the grievance was confirmed or not confirmed,~~ *and* any corrective action taken or to be taken by the facility as a result of the grievance~~, and the date the written decision was issued~~;

(vi) Taking appropriate corrective action in accordance with State law if the alleged violation of the residents' rights is confirmed by the facility or if an outside entity having jurisdiction, such as the State Survey Agency, Quality Improvement Organization, or local law enforcement agency confirms a violation of any of these residents' rights within its area of responsibility; and

(vii) Maintaining evidence demonstrating the results of all grievances for a period of no less than ~~3 years~~ *18 months* from the issuance of the grievance decision.

483.15 Admission, transfer, and discharge rights.

483.15(c)(3) Notice before transfer. Before a facility transfers or discharges a resident, the facility must—

(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. *For facility initiated involuntary transfers or discharges, other than emergency transfers to an acute care facility when return is expected,* the facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

ii) Record the reasons for the transfer or discharge in the resident's medical record in accordance with paragraph (c)(2) of this section; and

(iii) Include in the notice the items described in paragraph (c)(5) of this section.

483.25 Quality of care.

483.25(n) Bed rails. The facility must attempt to use appropriate alternatives prior to the use of a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements.

(1) Assess the resident for risk of entrapment from bed rails ~~prior to installation~~ *use*.

(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to ~~installation~~ *use*.

(3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.

(4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.

483.35 Nursing services.

483.35(g)(4) Facility data retention requirements. The facility must maintain the posted daily nurse staffing data for a minimum of ~~18 months~~ *15 months*, or as required by state law, whichever is greater.

483.40 Behavioral health services.

483.40(a) *In accordance with §483.35,* the facility must have sufficient staff who provide direct services to residents with ~~the appropriate~~ competencies and skills sets~~ to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with §483.70(e). These competencies and skills sets~~ *that* include, but are not limited to, knowledge of and appropriate training and supervision for:

(1) Caring for residents with mental and psychosocial disorders, as well as residents with a history of trauma and/or post-traumatic stress disorder, that have been identified in the facility assessment conducted pursuant to §483.70(e), and

(2) Implementing non-pharmacological interventions.

483.40(c) ~~If rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and rehabilitative services for mental disorders and intellectual disability, are required in the resident's comprehensive plan of care, the facility must—~~

~~(1) Provide the required services, including specialized rehabilitation services as required in §483.65; or~~

~~(2) Obtain the required services from an outside resource (in accordance with §483.70(g) of this part) from a Medicare and/or Medicaid provider of specialized rehabilitative services.~~

483.40~~(d)~~ *(c)* The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

483.45 Pharmacy services

483.45(e)(4) PRN orders for psychotropic drugs are limited to 14 days. ~~Except as provided in §483.45(e)(5), *i*~~*I*f the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, *the order can be extended in accordance with facility policy if* he or she ~~should~~ documents ~~their~~ *his or her* rationale in the resident's medical record and indicates the duration for the PRN order.

438.45(e)(5) ~~PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.~~ *It develops and maintains policies, standards, and procedures regarding the use of PRN orders for psychotropics, using recognized standards of practice, including the circumstances in which PRN orders for psychotropic drugs can be extended beyond 14 days. The policy must:*

(i) Take into consideration the facility's resident population, the individual residents' needs for psychotropic drugs, and their access to physicians and other health care practitioners; and

(ii) Include, at a minimum, the following elements:

(A) Standards regarding the frequency with which the attending physician or the prescribing practitioner must review the PRN order. The frequency of PRN review must be no less than the frequency of the required physician visits as set forth at §483.30(c).

(B) Documentation requirements regarding the diagnosis, indications for use, including nursing documentation describing the circumstances that support the administration of the medication, and justification for prolonged use.

(C) Disclosure requirements that the facility must make to the resident and his or her representative for when a resident is prescribed an anti-psychotic.

483.60 Food and nutrition services.

483.60(a)(2) If a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to serve as the director of food and nutrition services. ~~who—~~

(i) ~~For designations prior to November 28, 2016, meets the following requirements no later than 5 years after November 28, 2016, or no later than 1 year after November 28, 2016 for designations after November 28, 2016, is:~~

~~(A) A certified dietary manager; or~~

~~(B) A certified food service manager, or~~

~~(C) Has similar national certification for food service management and safety from a national certifying body; or~~

~~(D) Has an associate's or higher degree in food service management or in hospitality, if the course study includes food service or restaurant management, from an accredited institution of higher learning; and~~

(i) The director of food and nutrition services is one who at a minimum—

(A) Has two or more years of experience in the position of director of food and nutrition services in a nursing facility setting or;

(B) Has completed a course of study in food safety and management that includes topics integral to managing dietary operations such as, but not limited to, foodborne illness, sanitation procedures, and food purchasing/receiving.

~~(ii) In States that have established standards for food service managers or dietary managers, meets State requirements for food service managers or dietary managers, and~~

(ii) The director of food and nutrition services must receive frequently scheduled consultation from a qualified dietitian or other clinically qualified nutrition professional.

(iii) Receives frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional.

483.70 Administrative.

483.70(e) Facility assessment. The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must, *in accordance with §§483.35, 483.40(a), 483.60(a), and 483.75, utilize information collected under the facility assessment to inform policies and procedures;* review and update that assessment, as necessary, and at least ~~annually~~ *biennially; and* ~~. The facility must also~~ review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment. The facility assessment must address or include:

(1) The facility's resident population, including, but not limited to,

(i) Both the number of residents and the facility's resident capacity;

(ii) The care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present within that population;

(iii) The staff competencies that are necessary to provide the level and types of care needed for the resident population;

(iv) The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and

(v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.

(2) The facility's resources, including but not limited to,

(i) All buildings and/or other physical structures and vehicles;

(ii) Equipment (medical and non-medical);

(iii) Services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies;

(iv) All personnel, including managers, staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;

(v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and

(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.

~~(3) A facility-based and community-based risk assessment, utilizing an all-hazards approach.~~

483.75 Quality assurance and performance improvement program.

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.~~

483.75(c) Program feedback, data systems and monitoring. A facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring, including adverse event monitoring. ~~The policies and procedures must include, at a minimum, the following:~~

~~(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.~~

~~(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.~~

~~(3) Facility development, monitoring, and evaluation of performance indicators, including the methodology and frequency for such development, monitoring, and evaluation.~~

~~(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.~~

483.75(d) Program systematic analysis and systemic action. ~~(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.

~~(2) The facility will develop and implement policies addressing:~~

~~(i) How they will use a systematic 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.~~

483.80 Infection control.

483.80(b) Infection preventionist. The facility must designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's IPCP. The IP must:

(1) Have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field;
(2) Be qualified by education, training, experience or certification;
(3) ~~Work at least part-time at the facility~~ *Have sufficient time at the facility to achieve the objectives set forth in the facility's IPCP*.
(4) Have completed specialized training in infection prevention and control.

§483.85 Compliance and ethics program.

§483.85 (a) Definitions. For purposes of this section, the following definitions apply:
Compliance and ethics program means, with respect to a facility, a program of the operating organization that—
(i) Has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care; and
(ii) Includes, at a minimum, the required components specified in paragraph (c) of this section.
High-level personnel means individual(s) who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization.
Operating organization means the individual(s) or entity that operates a facility.

(b) General rule. Beginning November 28, 2019, the operating organization for each facility must have in operation a compliance and ethics program (as defined in paragraph (a) of this section) that meets the requirements of this section.

(c) Required components for all facilities. The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components:
(1) Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act ~~and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles~~.
(2) Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures~~, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization~~.
(3) Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures.
(4) Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.
(5) The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at §483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program.
(6) The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others ~~anonymously~~ within the operating organization without fear of retribution~~, and having a process for ensuring the integrity of any reported data~~.

(7) Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation *(statute says "offense")* to the compliance and ethics program contact identified in the operating organization's compliance and ethics program.
(8) After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act.
(9) The facility has an alternate method of reporting suspected violations anonymously.

(d) Additional required components for operating organizations with five or more facilities. In addition to all of the other requirements in paragraphs (a), (b), (c), and (e) of this section, operating organizations that operate five or more facilities *and facilities with corporate level management of multi-unit nursing home chains* must *comply with these additional requirements must* [sic] ~~also include, at a minimum, the following components in their compliance and ethics program~~:
(1) ~~A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in §483.95(f)~~ *Have a more formal program that includes established written policies defining the standards and procedures to be followed by its employees.*
(2) ~~A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility. This individual must report directly to the operating organization's governing body and not be subordinate to the general counsel, chief financial officer or chief operating officer~~ *Develop a compliance and ethics program that is appropriate for the complexity of the operating organizations and its facilities.*
~~(3) Designated compliance liaisons located at each of the operating organization's facilities.~~

(e) ~~Annual~~ *Program* review. The operating organization for each facility must *periodically* review its compliance and ethics program *to identify necessary changes within the organization and its facilities*~~. annually and revise its program as needed to reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in deterring, reducing, and detecting violations under the Act and in promoting quality of care~~.

483.90 Physical environment.

483.90 (a) Life safety from fire. (1) Except as otherwise provided in this section—
(i) The LTC facility must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.)
(ii) Notwithstanding paragraph (a)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.
(iii) If a facility is Medicare- or Medicaid-certified before July 5, 2016 and the facility has previously used the Fire Safety Evaluation System for compliance, the facility may use the scoring values in table 1 to § 483.90(a)(1)(iii):

Table 1 to § 483.90(a)(1)(iii): Mandatory Values—Nursing Homes

	Containment (Sa)		Extinguishment (Sb)		People Movement (Sc)	
Zone Location	New	Exist.	New	Exist.	New	Exist.
1st story	11	5	**15(12)***	4	**8(5)***	1
2nd or 3rd story**	15	9	**17(14)***	6	**10(7)***	3
4th story or higher	18	9	**19(16)***	6	**11(8)***	3

* Use ( ) in zones that do not contain patient sleeping rooms. [** appears in the table but no explanatory footnote is included]

483.90(d)Space and equipment. The facility must—
(1) Provide sufficient space and equipment in dining, health services, recreation, *living* and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's *assessment and* plan of care; and
(2) Maintain all ~~essential~~ mechanical, electrical, and patient care equipment in safe operating condition.
(3) *Conduct regular inspection of all bed frames, mattresses, and bed rails, if any, as part of a regular maintenance program to identify areas of possible entrapment. When bed rails and mattresses are used and purchased separately from the bed frame, the facility must ensure that the bed rails, mattress, and bed frame are compatible*.*

483.90(e) Resident rooms. Resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents. (1) Bedrooms must—
(i) Accommodate no more than four residents. For facilities that receive approval of construction ~~or reconstruction~~ plans by state and local authorities or are newly certified *and have never previously been a LTC facility,* after November 28, 2016, bedrooms must accommodate no more than two residents.
[483.90(e)(1)(ii) through (vii), (e)(2) and (e)(3) would remain unchanged]

483.90(f) Bathroom facilities. Each resident room must be equipped with or located near toilet and bathing facilities. For facilities that receive approval of construction from state and local authorities or are newly certified *and have never previously been a LTC facility,* after November 28, 2016, each resident room must have its own bathroom equipped with at least a commode and sink.

483.95 Training requirements.

483.95(f) Compliance and ethics. The operating organization for each facility must include as part of its compliance and ethics program, as set forth at §483.85 ~~(1)~~ ~~A~~*an* effective way to communicate that program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program.
~~(2) Annual training if the operating organization operates five or more facilities.~~

PART 488—SURVEY, CERTIFICATION AND ENFORCEMENT PROCEDURES

§488.331 Informal dispute resolution.

488.331(b)(1) ~~Failure of the State or CMS, as appropriate, to complete informal dispute resolution timely cannot delay the effective date of any enforcement action against the facility~~ *Informal dispute resolution will be completed within 60 days of the facility's request to dispute the survey findings if the request by the facility is timely. Failure of the state or CMS, as appropriate, to complete informal dispute resolution timely cannot delay the effective date of any enforcement action against the facility.*
(2) A facility may not seek a delay of any enforcement action against it on the grounds that informal dispute resolution has not been completed before the effective date of the enforcement action, *except that the results of the survey will not be uploaded into the CMS nursing home survey and certification database and/or used for the purposes of the CMS "Nursing Home Compare" website to calculate the facility's 5-star rating until the informal dispute resolution or the independent informal dispute resolution process is complete.*

§488.431 Civil money penalties imposed by CMS and independent informal dispute resolution: for SNFs, dually-participating SNF/NFs, and NF-only facilities

488.431 (a) Opportunity for independent review. CMS retains ultimate authority for the survey findings and imposition of civil money penalties, but provides an opportunity for independent informal dispute resolution within 30 days of notice of imposition of a civil money penalty that will be placed in escrow in accordance with paragraph (b) of this section. An independent informal dispute resolution will—
(1) Be completed within 60 days of facility's request if an independent informal dispute resolution is timely requested by the facility.
(2) Generate a written record prior to the collection of the penalty. *The state, or CMS, as applicable, will provide the facility with a written notification of the independent reviewer's recommendation and the final decision, including a rationale for that decision.*
(3) Include notification to an involved resident or resident representative, as well as the State's long term care ombudsman, to provide opportunity for written comment.

(4) Be approved by CMS and conducted by the State under section 1864 of the Act, or by an entity approved by the State and CMS, or by CMS or its agent in the case of surveys conducted only by federal surveyors where the State independent dispute resolution process is not used, and which has no conflict of interest, such as:

(i) A component of an umbrella state agency provided that the component is organizationally separate from the state survey agency, *and has a specific understanding of Medicare and Medicaid program requirements.*

(ii) An independent entity with a specific understanding of Medicare and Medicaid program requirements selected by the State and approved by CMS.

(5) Not include the survey findings that have already been the subject of an informal dispute resolution under §488.331 for the particular deficiency citations at issue in the independent process under §488.431, unless the informal dispute resolution under §488.331 was completed prior to the imposition of the civil money penalty

488.432 Civil money penalties imposed by the State: NF–only.

488.432(c)(2) If a facility waives~~, in writing,~~ its right to a hearing as specified in §488.436, the state initiates collection of civil money penalty imposed per instance of noncompliance ~~upon receipt of the facility's notification~~ *after 60 days and the state has not received a timely request for a hearing*.

§488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount

488.436(a) Constructive waiver of a hearing. ~~The facility may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty.~~ A facility is deemed to have waived its right to a hearing after 60 days if CMS has not received a request for a hearing from the facility.

§ 488.442 Civil money penalties: Due date for payment of penalty.

§488.442 Civil money penalties: Due date for payment of penalty. (a) When payments are due for a civil money penalty. (1) Payment for a civil money penalty is due in accordance with §488.431 of this chapter for CMS-imposed penalties and 15 days after the State initiates collection pursuant to §488.432 of this chapter for State-imposed penalties, except as provided in paragraphs (a)(2) and (3) of this section.

(2) ~~After a request to waive a hearing or when a hearing was not requested. Except as provided for in §488.431, a civil money penalty is due 15 days after receipt of a written request to waive a hearing in accordance with §488.436 or 15 days after the time period for requesting a hearing has expired and a hearing request was not received when~~: After the facility waives its right to a hearing in accordance with §488.436(a). Except as provided for in §488.431, a civil money penalty is due 75 days after the notice of the penalty and a hearing request was not received when:

(i) The facility achieved substantial compliance before the hearing request was due; or

(ii) The effective date of termination occurs before the hearing request was due.

NOTES:

- The proposed changes in 483.90(d)(1) and the addition of§483.90(d)(3) were adopted in the October 2016 final rule but inadvertently removed in a subsequent technical correction. CMS is proposing to properly correct the Code of Federal Regulations.
- The proposed rule would also make conforming and technical changes to regulatory text that are not shown in this summary table. Among these is a proposed change in the text at §485.645(d)(3) regarding swing beds in Critical Access Hospitals which references the application of paragraphs §483.12 (c)(1) through (6). However, there are no paragraphs §483.12 (5) or (6).