DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 482, 483, 485 and 488

[CMS–3347–P]

RIN 0938–AT36

Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions To Promote Efficiency, and Transparency

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would reform the Medicare and Medicaid long-term care requirements that the Centers for Medicare & Medicaid Services has identified as unnecessary, obsolete, or excessively burdensome. This rule would increase the ability of health care professionals to apportion resources to improving resident care by eliminating or reducing requirements that impede quality care or that divert resources away from providing high quality care.

DATES: To be assured consideration, comments must be received at one of the addresses provided, no later than 5 p.m. on September 16, 2019.

ADDRESSES: In commenting, please refer to file code CMS–3347–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3347–P, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3347–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: LTC Regulations Team, Ronisha Blackstone, Diane Corning, Mary Collins, Kristin Shifflett, Eric Laib, Lisa Parker, and Sheila Blackstock at (410) 786–6633.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

Over the past several years, we have revised the Conditions of Participation (CoPs), the Conditions for Coverage (CfCs), and requirements for long-term care (LTC) facilities to reduce the regulatory burden on providers and suppliers. We identified obsolete and burdensome regulations that could be eliminated or reformed to improve effectiveness or reduce unnecessary reporting requirements and other costs, with a particular focus on freeing up resources that health care providers, health plans, and states could use to improve and enhance resident health and safety. We have also examined policies and practices not codified in rules that could be changed or streamlined to achieve better outcomes for residents, while reducing burden on providers and suppliers of care, and we identified non-regulatory changes to increase transparency and to become a better business partner. In addition, the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) have reaffirmed their shared commitment to the vision of creating an environment where agencies incorporate and integrate the ongoing retrospective review of regulations into Department operations to achieve a more streamlined and effective regulatory framework. The objectives are to improve the quality of existing regulations consistent with statutory requirements; streamline procedural solutions for businesses to enter and operate in the healthcare marketplace; maximize net benefits (including benefits that are difficult to quantify); and reduce costs and other burdens on businesses to comply with regulations.

We are proposing changes to the current LTC requirements and survey process that would simplify and streamline the current requirements and thereby increase provider flexibility and reduce excessively burdensome regulations, while also allowing facilities to focus on providing high-quality healthcare to their residents. This proposed rule would also reduce the frequency of certain required activities and, where appropriate, revise timelines for certain facility requirements and remove obsolete, duplicative, or unnecessary requirements. We believe that these proposals balance resident safety and quality of care, while also providing regulatory relief for facilities.

2. Summary of Major Provisions

a. Requirements for Participation

Resident Rights (§ 483.10)

We propose to revise the requirement for facilities to ensure that residents remain informed of the name and specialties of the physician and other primary care professionals responsible for their care, and is provided with their contact information. Specifically, we propose to reduce burden by revising the provision to require facilities to provide residents with their primary care physician's name and contact information upon admission, with any change, or upon a resident's request.

In addition, we propose revisions to the grievance policy requirements. Proposed revisions include clarifying that general feedback may not rise to the level of an official grievance, removing the specific duties required of the grievance official, removing prescriptive requirements related to written grievance decisions, and reducing the amount of time that facilities must retain evidence demonstrating the results of grievances from 3 years to 18 months.

Admission, Transfer, and Discharge Rights (§ 483.15)

We propose to revise the requirement for facilities to send discharge notices to State LTC Ombudsman by applying this requirement to ''facility-initiated involuntary transfers and discharges'' only. This proposed revision would reduce the paperwork burden on facilities.

Quality of Care (§ 483.25)

We propose to modify requirements to focus on the appropriate ''use'' of bed

rails and eliminate references to the ''installation'' of bed rails. These revisions would provide clarity and address stakeholder concerns regarding the purchase of beds with bed rails already in place with no practical means of removal.

Nursing Services (§ 483.35)

We propose to reduce the timeframe that LTC facilities are required to retain posted daily nursing staffing data from 18 months to 15 months, or as required by state law. The proposed revision would reduce a paperwork burden on facilities.

Behavioral Health (§ 483.40)

We propose to remove requirements that are duplicative of other LTC requirements in other sections of the regulation, and improve clarity.

Pharmacy Services (§ 483.45)

We propose to remove the existing requirement that Pro re Nata (PRN), or as needed, prescriptions for anti-psychotics cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication. This proposed revision would increase flexibility by allowing each facility to allow for PRN orders of all psychotropic medications to be extended beyond 14 days if the attending physician or prescribing practitioner believes it appropriate and documents his or her rationale in the resident's medical record and indicates the duration for the PRN order. We have also solicited specific comments concerning this proposed modification.

Food and Nutrition Services (§ 483.60)

We propose to revise the required qualifications for a director of food and nutrition services to provide that those with several years of experience performing as the director of food and nutrition services in a facility could continue to do so. We propose that at a minimum an individual designated as the director of food and nutrition services would receive frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional; and would either have 2 or more years of experience in the position of a director of food and nutrition services, or have completed a minimum course of study in food safety that includes topics integral to managing dietary operations such as, but not limited to, foodborne illness, sanitation procedures, food purchasing/receiving, etc. This proposal would help to address concerns related to costs associated with training for existing staff and the potential need to hire new staff.

Administration (§ 483.70)

We propose to clarify that data collected under the facility assessment requirement can be utilized to inform policies and procedures for other LTC requirements. In addition, we propose to remove duplicative requirements and revise the requirement for the review of the facility assessment from annually to biennially.

Quality Assurance and Performance Improvement (§ 483.75)

We propose to revise the requirement for facilities to implement a Quality Assurance and Performance Improvement (QAPI) program by removing prescriptive requirements to allow facilities greater flexibility in tailoring their QAPI program to the specific needs of their individual facility.

Infection Control (§ 483.80)

We propose to remove the requirement that the infection preventionist (IP) work at the facility ''part-time'' or have frequent contact with the infection prevention and control program (IPCP) staff at the facility. We will instead require that the facility must ensure that the IP has sufficient time at the facility to meet the objectives of its IPCP. We will also include comment solicitations on this proposal.

Compliance and Ethics Program (§ 483.85)

We propose to remove many of the requirements from this section not expressly required by statute. Proposed revisions include removing the requirements for a compliance officer and compliance liaisons and revising the requirement for reviewing the program from annually to biennially.

Physical Environment (§ 483.90)

We propose to allow older existing LTC facilities to continue to use the 2001 Fire Safety Equivalency System (FSES) mandatory values when determining compliance for containment, extinguishment, and people movement requirements. This proposal would allow older facilities who may not meet the FSES requirements in the recently adopted 2012 Life Safety Code (LSC) to remain in compliance with the older FSES without incurring substantial expenses to change their construction types, while maintaining resident and staff safety.

In addition, we propose to revise the requirements that newly constructed, reconstructed, or newly certified facilities accommodate no more than two residents in a bedroom and equip each resident room with its own bathroom that has a commode and sink.

Specifically, we propose to only apply this requirement to newly constructed facilities and newly certified facilities that have never previously been a nursing home. This would remove unintended disincentives to purchase facilities or make upgrades to existing facilities.

Technical Corrections

We propose to correct several technical errors that have been identified in 42 CFR part 483 subpart B.

b. Survey, Certification, and Enforcement Procedures

Informal Dispute Resolution and Independent Informal Dispute Resolution (§ 488.331 and § 488.431)

We propose to revise the informal dispute resolution and independent informal dispute resolution processes to increase provider transparency by ensuring that administrative actions are processed timely, and that providers understand the outcomes of results.

Civil Money Penalties: Waiver of Hearing, Reduction of Penalty Amount (§ 488.436)

We propose to eliminate the requirement for facilities to actively waive their right to a hearing in writing and create in its place a constructive waiver process that would operate by default when CMS has not received a timely request for a hearing. The accompanying 35 percent penalty reduction would remain. This proposed revision would result in lower costs for most LTC facilities facing civil money penalties (CMP)s, and would streamline and reduce the administrative burden for stakeholders.

Phase 3 Implementation of Overlapping Regulatory Provisions

The revised LTC requirements for participation are being implemented in three phases. Phases 1 and 2 were implemented in November of 2016 and 2017, respectively. Phase 3 includes additional regulatory provisions that are scheduled to be implemented on November 28, 2019.

Of the Phase 3 provisions, this regulation proposes revisions that, if finalized, would have an impact on provisions that fall into three primary areas—(1) designation and training of the infection preventionist (§ 483.80), QAPI (§ 483.75), and compliance and

ethics program (§ 483.85). We propose to delay implementation of some these Phase 3 provisions until 1 year following the effective date of this regulation. We do not propose to delay those requirements related to the infection preventionist at § 483.80(b)(1) through (4), (c) and § 483.75(g)(1)(iv). This would avoid unnecessary work, confusion and burden associated with implementing provisions, which may then change in a final rule shortly thereafter.

3. Summary of Costs and Benefits

In this proposed rule we have identified reforms in more than a dozen major sections of the existing Code of Federal Regulations (CFR) pertaining to LTC facilities. Every proposed reform aims to reduce regulatory burdens on these facilities without jeopardizing any responsibilities or practices that maintain or improve resident care. The ''benefits'' of this proposed rule are its cost reductions, and there are no known ''costs'' imposed by this regulation. Our proposals and these conclusions are explained throughout this preamble, and we welcome additional information on each, suggested improvements, additional reform proposals, and any other comments.

In total, we have identified and proposed reductions in information collection burden whose annual costs today, and future annual savings will be approximately $59 million. We propose other reforms in current regulations that will generate annual savings in operating costs of almost $210 million. We also propose reducing punitive facility construction requirements that will save in excess of $325 million in costs over each of the next 5 years. Total estimated cost savings over each of the first 5 years are approximately $616 million.

B. Background

1. Statutory and Regulatory Authority of the Long-Term Care Requirements

The provisions contained in this proposed rule are authorized by the general rulemaking authority for the Secretary of the Department of Health and Human Services (the Secretary) under sections 1102 and 1871 of the Act, which afford the Secretary broad authority to promulgate such regulations as may be necessary to administer the Medicare and Medicaid programs.

In addition, the Secretary has statutory authority to issue these rules under the Nursing Home Reform Act, (part of the Omnibus Budget Reconciliation Act of 1987 (''OBRA '87''), (Pub. L. 100–203, 101 Stat. 1330 (1987)), which added sections 1819 and 1919 to the Act; those provisions authorize the Secretary to promulgate regulations that are ''adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys.'' (Sections 1819(f)(1) and 1919(f)(1) of the Act). In addition, the Act authorizes the Secretary to impose ''such other requirements relating to the health and safety [and well-being] of residents as [he] may find necessary.'' (Sections 1819(d)(4)(B), 1919(d)(4)(B) of the Act). Under Sections 1819(c)(1)(A)(xi) and 1919 (c)(1)(A)(xi) of the Act, the Secretary may also establish ''other right[s]'' for residents, in addition to those expressly set forth in the statutes and regulations, to ''protect and promote the rights of each resident.''

Section 1864(a) of the Act authorizes the Secretary to enter into agreements with state survey agencies (SAs) to determine whether facilities meet the Federal participation requirements for Medicare. Section 1902(a)(33)(B) of the Act provides for SAs to perform the same survey tasks for facilities participating or seeking to participate in the Medicaid program. The results of Medicare and Medicaid related surveys are used by Centers for Medicare and Medicaid Services (CMS) and the State Medicaid agency, respectively, as the basis for a decision to enter into or deny a provider agreement, recertify facility participation in one or both programs, or terminate the facility from the program. They are also used to determine whether one or more enforcement remedies should be imposed where noncompliance with federal requirements is identified.

2. October 2016 Long-Term Care Final Rule

On October 4, 2016, we issued a final rule entitled, ''Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities'' (81 FR 68688). This final rule significantly revised the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. Prior to the final rule, the LTC requirements had not been comprehensively reviewed and updated since 1991 (56 FR 48826, September 26, 1991), despite substantial changes in service delivery in this setting. The final rule included revisions that reflect advances in the theory and practice of service delivery and safety. In addition, the various revisions sought to achieve broad-based improvements in the quality of care provided in LTC facilities and in resident safety.

We received mixed reactions from LTC stakeholders in response to our revision of the LTC requirements. Overall, all stakeholders supported the regulation's focus on person-centered care and agreed that reforms to the existing requirements were necessary to support high quality care and quality of life in LTC facilities. While supportive of the goals of the regulation, some industry stakeholders noted that some of the changes needed to comply with the revised requirements would be costly and burdensome. Given the scope of the revisions, stakeholder requests for more time to comply with the requirements, and the financial impact that the regulation would impose on LTC facilities, we finalized a phased-in implementation of the requirements over a 3-year time period with the goal of reducing some of the burden placed on LTC facilities. Readers may refer to the October 2016 final rule (81 FR 68696) for a detailed discussion regarding the implementation timeframes for the requirements. In addition, we established an 18-month transition period for facilities who fall short on complying with the November 28, 2017 implementation of the Phase 2 Requirements of Participation. There would be a temporary 18-month moratorium on the imposition of civil money penalties, discretionary denials of payment for new admissions and discretionary termination where the remedy is based on a deficiency finding of the certain Phase 2 requirements; however, facilities would be required to invest in staff education and to come into compliance as quickly as possible (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-04.pdf*).

3. Comment Solicitation in the Fiscal Year (FY) 2018 Skilled Nursing Facility Prospective Payment System (SNF PPS) Proposed Rule

In the FY 2018 Skilled Nursing Facility Prospective Payment System (SNF PPS) proposed rule (82 FR 21014) published in the **Federal Register** on May 4, 2017, we solicited comments for feedback regarding areas of burden reduction and cost savings in LTC facilities. We received 184 public comments in response to our request for comments. Commenters included LTC facilities, LTC consumers, LTC advocacy groups, many individual healthcare professionals, and various health care organizations and associations.

In the FY 2018 SNF PPS proposed rule we also discussed potential areas for burden reduction including

revisions to the 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). Commenters also provided additional suggestions for burden reduction. The majority of the additional suggestions were related to removing the requirement for a facility assessment and increasing the timeframe associated with reporting suspicions of resident abuse. One commenter provided a detailed financial analysis of their costs so far related to implementing their QAPI, Infection Control, and Compliance and Ethics programs. We also received additional comments related to the survey process and requirements for providing payroll-based journal data at § 483.75(u) (as implemented in the August 4, 2015 final rule entitled, ''Medicare Program; Prospective Payment System (PPS) and Consolidated Billing for Skilled Nursing Facilities (SNF) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection'' (80 FR 46389). Furthermore, several commenters also recommended that we not revise the requirements for purposes of reducing burden on facilities at the expense of the safety and quality of care provided to residents. These commenters noted that the true impact of the requirements cannot be assessed, as the majority have not yet been implemented.

In combination with our internal review of the existing regulations, we have used stakeholder feedback to inform our policy decisions with regard to the proposals discussed in this rule. We note that we considered all of the stakeholder recommendations and specifically considered how each recommendation could potentially reduce burden without impinging on the health and safety of residents. In addition, we note that we are committed to transforming the health care delivery system—and the Medicare program—by putting an additional focus on person-centered care and working with providers, physicians, and residents to improve outcomes. We seek to reduce burdens for facilities and residents, improve the quality of care, decrease costs, and ensure that residents, their providers and physicians are making the best health care choices possible. Therefore, we are soliciting public comments on additional regulatory reforms for burden reduction. We specifically are seeking public comment on additional proposals or modifications to the proposals set forth in this rule that would further reduce burden on facilities and create cost savings, while also preserving quality of care and resident health and safety. Consistent with our ''Patients Over Paperwork'' Initiative, we are particularly interested in any suggestions to improve existing requirements, within our statutory authority, where they make providing quality care difficult or less effective. The most useful comments will be those that include data or evidence to support the position, offer suggestions to amend specific sections of the existing regulations, or offer particular additions.

II. Provisions of the Proposed Regulations

A. Requirements for Participation

1. Resident Rights (§ 483.10)

Choice of Attending Physician

Section 483.10(d)(3) requires that facilities ensure that a resident remains informed of the name and specialties of the physician and other primary care professionals responsible for his or her care, and is provided with their contact information. While understanding that residents are often under the care of multiple healthcare professionals, we can see how this requirement could have the potential to substantially burden facilities with maintaining an exhaustive list of professionals for each resident. In addition, we understand that the use of ''remain informed'' is vague and may impose unnecessary burdens on both the facility and residents to meet this requirement. Therefore, we propose to revise this provision to remove the language indicating that facilities must ensure that residents remain informed and would instead specify that residents be informed of only their primary care physician's information at admission, with any change of such information, and upon the resident's request. We believe that this proposal clarifies the intent of the requirement, which is to ensure that a resident knows the name and contact information for the individual(s) primarily responsible for their care. The revision would ultimately reduce burden on facilities by specifically detailing their responsibilities under this requirement. We request additional feedback 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, we are interested to learn 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.

Grievances

The October 2016 final rule finalized a proposal at § 483.10(j) to extensively expand the grievance process in LTC facilities. Specifically, facilities are required to establish a grievance policy to ensure the prompt resolution of grievances and identify a grievance officer to oversee the process. LTC stakeholders have supported the enhancement of residents' rights to voice grievances and emphasize the importance and seriousness of resident concerns. However, other industry stakeholders have also indicated that the expansion of the requirements for a grievance process is overly burdensome and costly, specifically with regard to maintaining evidence related to grievances, and staffing a grievance official.

After further consideration, we believe that revisions can be made to these requirements to minimize prescriptiveness, while maintaining facility accountability. We are also requesting additional feedback regarding how to minimize burden while taking into account the rights of residents, and the additional burden on residents and long-term care ombudsmen if the proposed revisions to the requirements at § 483.10(j) are made. Specifically, we propose to revise § 483.10(j)(1) by adding language that would clarify the difference between resident feedback and a grievance. Section 483.10(j)(1) would be revised to state that 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 have been furnished as well as those which have not been furnished, the behavior of staff and of other residents; and other concerns regarding their LTC facility stay that differ from general feedback provided by the resident or their resident representatives. We believe that the addition of this language would help to streamline a facility's grievance process and ensure that the grievance process focuses on concerns that rise to the level of an official grievance. We believe that a streamlined process would increase efficiency and facility response to grievances, which will have a positive impact on a resident's ability to voice

their grievances and have them resolved promptly. Furthermore, we believe that general feedback or complaints stem from general issues that can typically be resolved by staff present at the time a concern is voiced, while grievances are more serious and generally require investigation into allegations regarding the quality of care. It would be the facility's responsibility to include how they made this determination as to whether a comment was a grievance or general feedback as part of their grievance policy and ensure that residents were fully informed of such determination.

We believe that the added language provides clarification without impeding on a resident's right to voice grievances. However, we want to emphasize that a resident's right to voice grievances and a facility's responsibility to make prompt efforts to resolve grievances fully remains. We expect that in the event a facility has not addressed general feedback provided repeatedly by a specific resident, or the same feedback filed by different residents, such lack of a resolution by the facility would raise their concerns to that of a grievance. Therefore, we would expect that as a general practice, facilities would continue to make every effort to resolve resident concerns before the grievance process is initiated. Nonetheless, we note that certain systems continue to be in place if a resident believes that their rights have been ignored or not appropriately addressed by the facilities. These include raising their concerns through the Ombudsman program, State Survey Agency, or the Quality Improvement Organization (QIO) program.

We also propose to revise § 483.10(j)(2) to remove the phrase ''by the facility.'' The revision would read as follows, ''the resident has the right to, and the facility must make prompt efforts to, resolve grievances the resident may have, in accordance with this paragraph.'' We believe that this revision does not make any substantive changes, but would remove unnecessary language and improve readability. The facility's responsibility to make prompt efforts to resolve resident grievances fully remains.

At § 483.10(j)(4)(ii), we propose to remove the specific duties required of the grievance official who is responsible for overseeing the grievance process. We believe that this revision would address facility stakeholder concerns by allowing facilities greater flexibility in determining how their individual facility will ensure grievances are fully addressed. We note that facilities have the flexibility to assign the role of grievance official to existing staff, and the existing requirements do not prohibit facilities from assigning multiple or additional individuals to assist the grievance official in the oversight of the facility's grievance process. We do not believe that this proposal will have a negative impact on residents because residents will still have a specific individual(s) to directly report to their grievances. In addition, existing requirements at § 483.10(j)(3) also require facilities to make information on how to file a grievance or complaint available to the resident. This proposal does not impede on a resident's right to voice grievances, but rather removes prescriptiveness and allows facilities some flexibility in delegating the responsibilities of the grievance official.

Section 483.10(j)(4)(v) requires facilities to ensure 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, 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, 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. We propose to revise § 483.10(j)(4)(v) to require facilities to ensure that any written grievance decisions include any pertinent information including but not limited to a summary of the findings or conclusions and any corrective actions. We expect that information, such as the date the grievance was received and a summary statement of the resident's grievance, is included as a standard practice to ensure that the written decision is complete and informative. This revision would remove much of the specificity included in the provision in an effort to focus on the true intent of the requirement, which is to clearly inform residents of grievance decisions and any corrective actions.

Lastly, we propose to revise § 483.10(j)(4)(vii), to require facilities to maintain evidence demonstrating the results of all grievances for a period of no less than 18 months from the issuance of the grievance decision. We are not proposing to remove the requirement to maintain records because we believe that record retention related to grievances protects both facilities and residents. Instead, we are proposing a timeframe of 18 months, as this time period would cover the longest possible interval between surveys for a facility (plus a few months) and provide a sufficient amount of information for investigations during a survey. Reducing this timeframe to 18 months from the existing requirement of 3 years, would uphold facility accountability while reducing the burden associated with maintaining records.

We request additional feedback regarding any unintentional consequences related to shortened timeframes for record retentions and whether there may be a need to retain records of grievances longer than a survey cycle.

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

Regulations at § 483.15(c)(3)(i) require LTC facilities to send transfers or discharge notices to the State LTC Ombudsman. As part of the FY 2018 SNF PPS proposed rule comment solicitation as previously discussed (82 FR 21014) we received valuable feedback from LTC stakeholders, including representatives of various Offices of State Long-Term Care Ombudsman, regarding a LTC Ombudsman's capacity to receive and review these notices. Stakeholders have indicated that there are some states that currently require involuntary discharge notices to be shared with the State LTC Ombudsman offices with requirements outlined for notification.

We also received valuable feedback with regard to the extent that a LTC Ombudsman will use this information once received. Stakeholders indicated that LTC Ombudsman programs are currently receiving notices and use the information to help individual residents, track trends, and advocate for systems changes to reduce inappropriate discharges.

After considering all of the feedback received and re-evaluating this requirement, we believe that the requirement is valuable; however, further clarification in the requirements is necessary to achieve the intended objective of reducing inappropriate discharges. Therefore, we propose to revise § 483.15(c)(3)(i) to specify that facilities must send a copy of a transfer or discharge notice to a representative of the Office of the State Long-Term Care Ombudsman only in the event of facility-initiated involuntary transfers or discharges. We note that this would not include residents who request the transfer, or who are transferred, on an emergency basis to an acute care facility when return is expected. We are soliciting comments on whether the requirement to send copies of transfer notices to the LTC Ombudsman should apply to transfers made on an emergency basis to an acute care facility, regardless of return status and

how this information, when a resident is expected to return, may be beneficial.

Furthermore, by ''facility-initiated'' involuntary transfer or discharge we mean a transfer or discharge that the resident objects to, did not originate through a resident's verbal or written request, and/or is not in alignment with the resident's stated goals for care and preferences. We encourage readers to refer to the Interpretive Guidance for additional information regarding when this requirement does and does not apply at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.*

We believe that this revision continues to support our goal of protecting residents in instances of involuntary transfers and discharges and reduces burden by streamlining the notification process to focus only on involuntary transfers or discharges. Streamlining this requirement would also improve resident access to the services of the Ombudsman program to assist during the discharge process by allowing Ombudsman offices to focus directly on inappropriate and involuntary discharges by facilities.

3. Quality of Care (§ 483.25)

Regulations in § 483.25 set forth requirements for numerous aspects of care and special needs of LTC facility residents. Regulations at § 483.25(n) require facilities to attempt to use appropriate alternatives prior to installing a side or bed rail. Section 483.25(n)(1) through (4) specifies requirements for when a facility uses bed or side rails. Specifically, facilities must ensure correct installation, use and maintenance of bed rails, including assessing the resident for the risk of entrapment from bed rails prior to installation, reviewing the risks and benefits of bed rails with the resident and obtaining informed consent prior to installation, ensuring that the resident's size and weight are appropriate for the bed's dimensions, and following the manufacturers' recommendations and specifications for installing and maintaining bed rails.

We received several inquiries from LTC stakeholders, as well as surveyors regarding these requirements and CMS' intent. Specifically, stakeholders have indicated that often times beds are purchased with bed rails already installed. In these instances, industry stakeholders are concerned with the inspection requirements ''prior to installation,'' specifically whether they are required to remove these bed rails or whether they can remain on beds, but not in use. Furthermore, if removal is required industry stakeholders have shared concerns regarding warranty agreements and surveyors have questioned how to evaluate compliance in these instances.

We agree that revisions are necessary to improve clarity. Given the potential risks associated with the use of bed rails, including accident hazards and physical restraint, this requirement is intended to ensure that facilities attempt alternatives prior to installing bed rails and ensure that resident safety is considered if/when they are being used. To clarify this, we propose to revise § 483.25(n) to remove references to the ''installation'' of bed rails and replace them with the ''use'' of bed rails. These revisions would focus on the appropriate use of bed rails when alternatives to bed rails are not feasible and address concerns related to the use of beds with bed rails already installed.

4. Nursing Services (§ 483.35)

Regulations in § 483.35 address certain aspects of LTC facility staffing and the need to consider the competencies of staff and resident acuity. Regulations at § 483.35(g) require facilities to post daily nurse staffing data that includes, among other information, the total number and the actual hours worked by licensed and unlicensed nursing staff directly responsible for resident care per shift. Section 483.35(g)(4) requires facilities to maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by state law, whichever is greater. We understand that some industry stakeholders believe that the new requirements for payroll-based journal (PBJ) staffing reporting at § 483.70(g) may be similar to the requirement at § 483.35(g)(4). Specifically, regulations at § 483.70(g) require facilities to electronically submit to CMS complete and accurate direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by CMS.

These regulations differ in that the requirements at § 483.70(g) provide a retrospective reporting of staffing so consumers can understand the type of staffing that exists in a facility on an average day, while the requirements at § 483.35(g) of daily postings provide real time information for residents and their families so that they are informed of who is working and the amount of staff working in their facility during a specific shift.

Therefore, we believe that both requirements are necessary. However, we believe that we may provide some flexibility in the regulations at § 483.35(g)(4) regarding the timeframe for retaining the posted information. We propose to revise § 483.35(g)(4) by reducing the timeframe for the retention of the nurse staffing data from 18 months to 15 months. We believe that 15 months of this facility-stored data would be sufficient to support any potential surveyor investigations.

5. Behavioral Health (§ 483.40)

Regulations at § 483.40 require facilities to provide the necessary behavioral health care and services for their residents to attain or maintain their highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Behavioral health is defined as encompassing a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders. Facilities must also have sufficient staff who provide direct services to the residents with the appropriate competencies and skill sets to provide nursing and related services. LTC stakeholders have recommended that we eliminate this section entirely or reconsider the requirements to address burden and avoid turning LTC facilities into mental health institutions. LTC stakeholders have also indicated that the regulations lack clarity and noted that there may be duplication of the requirements in this section elsewhere.

In further reviewing § 483.40, we continue to believe that a focus on the care and treatment for residents with mental disorders or psychosocial adjustment difficulties is necessary. Therefore, we are not proposing to eliminate this section, as suggested by some stakeholders. However, during our review of these requirements we identified areas of duplication that could be eliminated. We are proposing revisions to this section to improve clarity and ensure that our regulations clearly reflect what we require from facilities.

Specifically, § 483.40(a) requires facilities to have sufficient staff who provide direct services to residents with the appropriate competencies and skill sets to provide nursing and related services, in accordance with a facility's assessment (§ 483.70(e)). This requirement duplicates the requirements at § 483.35, ''Nursing Services,'' which specify the general requirements for sufficient staff. To simplify the overall requirement, we propose to remove the duplicative language in § 483.40(a). This revision

would clearly articulate the intent of this requirement, which is to inform facilities of their responsibility to provide sufficient staff members who possess the basic competencies and skills sets to meet the behavioral health needs of residents for whom the facility has assessed and developed care plans.

Likewise, in further reviewing this section we have determined that § 483.40(c) is identical to the requirements in § 483.65(a), ''Specialized Rehabilitative Services.'' Therefore, we are proposing to remove § 483.40(c) from this section.

In addition, to these proposed revisions, we encourage those stakeholders seeking further clarity regarding the implementation of the Behavioral Health requirements, as well as the other regulatory sections, to look to the Interpretive Guidelines as a valuable resource. On June 20, 2017, CMS released Interpretive Guidelines for the LTC requirements for participation (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf*), which were developed with input from a variety of stakeholders including industry, clinical, and advocacy organizations.

6. Pharmacy Services (§ 483.45)

The existing regulations at § 483.45(e)(4) require that PRN prescriptions for psychotropic drugs be limited to 14 days. However, if the attending physician or prescribing practitioner believes it is appropriate for a PRN prescription order to be extended beyond 14 days, he or she may document their rationale in the resident's medical record and indicate the duration of the PRN order. However, that exception does not extend to anti-psychotics, which are limited to 14 days, unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication, as set forth at current § 483.45(e)(5).

We received feedback from the provider community concerning the burden resulting from the limitations on PRN orders for psychotropic drugs. These commenters said that the 14-day limitation could negatively impact the resident care. Many facilities, especially those that are small or in rural areas, already have difficulty with access to physicians and other health care providers, especially mental health practitioners. They were very concerned that there could be interruptions in resident care due to PRN orders expiring according to the § 483.45(e)(4) and (5) and not being renewed or getting another order before that time. To avoid not being in compliance with the requirements for PRN orders, some commenters were concerned that prescribers would write routine orders that would result in residents receiving more of the drug more often than if it were given PRN or only as needed.

We have also received feedback from both providers that primarily focused their comments on the burden imposed by the PRN requirements and advocates for residents that focused their comments on residents' rights. For example, a large organization representing mental health professionals indicated that they fully understood the need for safeguards to protect residents from inappropriate prescribing practices that place the convenience of the caregivers above the residents' interests. However, they also stated that the policies CMS had instituted on psychotropic drugs, were interfering with psychiatrists being able to appropriately treat residents with mental health and substance abuse disorders. They pointed to the increased scrutiny surrounding psychotropic medications, as well as the requirement for gradual dose reductions. They stated that the requirement for the in-person evaluation for residents who were on a PRN order for an anti-psychotic was unrealistic considering the access to care issues in several care settings. In addition, they were concerned about what they described as ''minimal standardized guidance provided to CMS surveyors'' that had resulted in ''improper rejections/citations for *appropriate* pharma-therapeutic decisions and documentation by psychiatrists, and this has become very detrimental to their patients'' while resulting in a significant administrative burden. This perspective demonstrates that while providers want to provide quality care to residents they can be frustrated with increased administrative burden and pressure to not use medications they believe are appropriate for the residents they care for.

Another perspective is evident in a report published on February 5, 2018, by the Human Rights Watch (HRW), ''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*).

This report describes their findings based on visiting numerous nursing homes, interviewing nursing home residents, their families, the facility staff, and other officials and experts in LTC care, including LTC ombudsmen, as well as an analysis of publically available data, including academic studies. This report found, among other things, that anti-psychotic medications were being used as chemical restraints and for the convenience of the staff in LTC facilities. Residents that were interviewed described how traumatic it was to lose their ability to stay awake, think, and communicate. The report also noted that a review of the data, as well the interviews, suggested that some nursing homes are circumventing the pressure to reduce anti-psychotic drug use by seeking an appropriate diagnosis from a physician that would justify the use of these drugs for a resident, typically schizophrenia. This concern was significant enough for numerous organizations to issue a joint statement on ''Diagnosing Schizophrenia in Skilled Nursing Centers.'' [1] that read, in part, ''[w]hile there is a national need for better and more approved treatments for behavioral and psychiatric symptoms in dementia, clinicians need to be mindful of, and avoid, labeling patients with other diagnoses to justify the use of medications or other treatments.''

In proposing changes to the PRN requirements for psychotropic medications, which include anti-psychotic drugs, we must ensure that the proposed requirements provide sufficient protections for residents from receiving inappropriate or unnecessary drugs and that medications are prescribed for residents based on their health care needs and not for the convenience of the staff or any other inappropriate reasons. However, we must also be mindful not to propose requirements that are overly burdensome to the facilities and health care providers that do not contribute to the quality of care for the residents, especially if they could result in interfering with residents receiving appropriate care for their health care needs.

Based on further consideration and the feedback we received, we agree that the current requirements could result in interruptions to some residents' care that could have a negative impact. Therefore, we propose to revise § 483.45(e)(4) and (5). Revised § 483.45(e)(4) would state that ''PRN orders for psychotropic drugs are limited to 14 days. If the attending physician or prescribing practitioner

[1] ''Joint Summary Statement—Diagnosing Schizophrenia in Skilled Nursing Centers,'' press release, The Society for Post-Acute and Long-Term Care Medicine, February 21, 2017, *http://www.paltc.org/newsroom/joint-summary-statement diagnosing-schizophrenia-skilled-nursing-centers* (accessed August 20, 2018).

believes that it is appropriate for the PRN order to be extended beyond 14 days, the order can be extended in accordance with the facility's policy if he or she documents his or her rationale in the resident's medical record and indicates the duration for the PRN order.'' Thus, there would be no distinction between anti-psychotics and other psychotropic medications. Section 483.45(e)(5) would be revised to require, in addition to the current requirements, that the facility's policies, standards, and procedures use recognized standards of practice; including the circumstances upon which PRN orders for psychotropic drugs could be extended beyond the 14-day limitation; and that the facility take into consideration individualized resident' needs for psychotropic drugs. We believe that having the same requirements for all psychotropic drugs will simplify the survey process and reduce improper deficiency citations, as well as remove potential obstacles for mental health professionals to provide quality care for residents. We believe that these changes will provide the flexibility that facilities and providers need to assure that they can care for their residents without excessive administrative burden.

We have not indicated any specific ''recognized standards of practice.'' We expect that experts in medicine and pharmacology would develop national standards that could be used in LTC facilities. In addition, we would be interested in any comments on standards that could be used to satisfy this requirement. We would also expect the mental health professionals that practice in the facility, as well as the medical director and director of nursing for the facility, would have significant input into the facilities' policies.

We remain concerned about the potential misuse of psychotropic drugs, especially anti-psychotics. Therefore, we are soliciting comments on whether these proposed modifications to the requirements concerning PRN orders for psychotropic drugs provide sufficient protection for residents. We welcome feedback on whether CMS should retain the current PRN policy for anti-psychotic drugs. We are also interested in additional information 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 necessary medications, interruptions in resident care, or any other consequences of retaining the current PRN policy for anti-psychotic drugs. In addition, we welcome feedback regarding alternative policy options that CMS could take to address concerns surroundings PRN orders of psychotropic drugs and an explanation of how such alternative policy options would provide resident protections, without limiting a resident's access to necessary medications. Furthermore, we are requesting feedback as to 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, we request that commenters provide recommendations to improve these proposed requirements. Lastly, we request feedback as to 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 evaluation should be required?

7. Food and Nutrition Services (§ 483.60)

Dietary standards for residents of LTC facilities are critical to both quality of care and quality of life. The October 2016 final rule extensively revised the requirements related to food and nutrition services, including a burden reducing requirement that allows a resident's attending physician to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of prescribing a resident's diet to the extent allowed by state law. In addition, the October 2016 final rule established qualifications for a director of food and nutrition services when a dietitian is not employed by a facility full-time. Specifically, regulations at § 483.60(a)(2)(i) state that 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. Under the existing regulations, the director of food and nutrition services must be a certified dietary manager; a certified food service manager; have similar national certification for food service management and safety from a national certifying body; or have an associate's or higher degree in food service management or in hospitality (if the course study includes food service or restaurant management). Individuals designated as the director of food and nutrition services prior to November 28, 2016, have 5 years to obtain the specified credentials and an individual designated after November 28, 2016, have 1 year to obtain the specified credentials. Furthermore, § 483.60(a)(2)(ii) specifies that the director of food and nutrition services could satisfy this requirement if they have met applicable state requirements to be a food service manager or dietary manager.

LTC stakeholders have shared concerns regarding the requirement that existing staff become certified dietary managers or food service managers. Specifically, industry stakeholders have concerns regarding the need for existing dietary staff, who are experienced in the duties of a dietary manager and currently operate in the position, to now obtain new or additional training to become qualified under the requirements. We believe that effective management and oversight of the food and nutrition service is critical to the safety and well-being of all residents of a nursing facility. Therefore, we continue to believe that it is important that there are standards for the individuals who will lead this service. However, after further consideration of stakeholder feedback, we understand that the move from no established standards prior to the October 2016 final rule for a director of food and nutrition services, to the level of standards established in the October 2016 final rule, may have subjected facilities to unnecessary burden and increased costs. Furthermore, despite the timeframes built into the requirements for existing and newly hired staff to obtain the specified credentials, we understand that facilities are concerned about a workforce shortage of certified dietary managers and the financial costs imposed on existing experienced staff to obtain specialized training.

Therefore, we propose to revise the standards at § 483.60(a)(2) to increase flexibility, while providing that the director of food and nutrition services is an individual who has the appropriate competencies and skills necessary to oversee the functions of the food and nutrition services. Specifically, we propose to revise the standards at § 483.60(a)(2)(i) and (ii) to provide that at a minimum an individual designated as the director of food and nutrition services is one who has 2 or more years of experience in the position of a director of food and nutrition services or has completed a minimum course of study in food safety that includes topics integral to managing dietary operations such as, but not limited to, foodborne illness, sanitation procedures, and food purchasing/receiving. We are retaining the existing requirement at § 483.60(a)(2)(iii) which specifies that the director of food and nutrition services must receive frequently scheduled consultations from a

qualified dietitian or other clinically qualified nutrition professional. These proposed revisions would maintain established standards for the director of food and nutrition services given the critical aspects of their job function, while addressing concerns related to costs associated with training existing staff and the potential need to hire new staff.

8. Administration (§ 483.70)

The existing regulations at § 483.70(e) require each facility to conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents during both day to-day operations and emergencies. The facility assessment requirement is intended to be used by the facility for multiple purposes, including, but not limited to, activities such as determining staffing requirements, establishing a QAPI program and conducting emergency preparedness planning.

Currently, the facility must review and update that assessment, as necessary, and at least annually. The facility must 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. LTC providers are to address in the facility assessment the facility's resident population (that is, number of residents, overall types of care and staff competencies required by the residents, and cultural aspects), resources (for example, equipment, and overall personnel), and a facility-based and community-based risk assessment.

We have received feedback from the provider community and other stakeholders stating that the facility assessment requirements at § 483.70(e) are excessively burdensome because they require information collection similar, but not identical, to other information collections required by the regulations. They stated that these requirements are very detailed and that they micro-manage how SNF/NFs must operate their businesses. They also stated that complying with existing provisions requires an immense amount of administrative time and that this reduces valuable leadership time that can be used for resident care. After a careful review of the current requirements, we propose to reduce burden by removing unnecessary requirements and clarify that data collected under the facility assessment requirement can be utilized to inform policies and procedures for other LTC requirements. For example, the requirements for Nursing services (§ 483.35), Behavioral health services (§ 483.40(a)) and Food and nutrition services (§ 483.60(a)) would all be able to utilize data from the facility assessment. In addition, the current QAPI requirement at § 483.75(c) requires facilities to establish requirements for QAPI program feedback, data systems and monitoring. Facilities must maintain effective systems to obtain and use feedback and input from direct care/direct access workers, other staff, residents, resident representatives and families to identify opportunities for improvement. The data collected under the QAPI requirement could be used to meet portions of the facility assessment requirements and vice versa. Many of the health and safety requirements were developed to complement and support each other to ensure optimum health and safety for the beneficiaries. In addition, we have identified some of the LTC requirements that are duplicative of requirements for emergency preparedness. LTC facilities are required under § 483.73(a) to develop and maintain an emergency preparedness plan that must be based on a documented facility-based and community-based risk assessment, utilizing an all-hazards approach. The emergency preparedness requirements that were effective on November 15, 2016, under § 483.73(a) also require LTC facilities to conduct a facility and community-based risk assessment. The emergency preparedness requirements are very detailed and discuss the full range of requirements for a facility to have an emergency plan, conduct a risk assessment, have policies and procedures, a communication plan, and conduct training and testing. As such, we are proposing to remove the unnecessary requirement at § 483.70(e)(3) that requires each facility to conduct and document a facility-wide assessment for both day to-day operations and emergencies.

The requirements at § 483.70(e)(1) through (2) will remain. We are proposing to change the minimum frequency in which a facility should conduct a facility assessment under this requirement from an annual assessment to a biennial facility-wide assessment. We note that this does not preclude facilities from conducting an assessment more frequently than every 2 years. We believe 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. Facilities must present their QAPI plan at each annual recertification survey and upon request during any other survey and to CMS upon request. The QAPI program must be ongoing, comprehensive, and address the full range of care and services provided by the facility and must present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with the program requirements. Thus, we believe 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. We believe that this would further reduce burden and improve administrative flexibility, especially for rural providers with limited resources.

9. Quality Assurance and Performance Improvement Program (§ 483.75)

Section 1128I of the Act, added by section 6102 of the Affordable Care Act, requires the Secretary to establish and implement a QAPI program for LTC facilities. LTC stakeholders have shared concerns with us regarding the prescriptiveness of the QAPI regulations implemented in the October 2016 final rule. Specifically, some industry stakeholders have indicated that they believe that the QAPI regulations are inflexible and too detailed, making it difficult for facilities to identify organizational priorities for improvement. However, resident advocates indicated that the QAPI process is new in the LTC setting and specificity in the requirements is necessary to ensure consistency and efficacy of the QAPI process.

After further consideration and a review of stakeholder feedback, we believe that the level of specificity and detail in the QAPI requirements, established in the October 2016 final rule, may limit a facility's ability to design their QAPI program to fit their individual needs and hinder a facility's QAPI program from being a valuable tool in promoting quality care. Therefore, we are proposing to revise the requirements to allow facilities more flexibility.

We note that we are not proposing to revise the existing language at § 483.75(a)(1) through (4). Section 483.75(a) requires each LTC facility, including a facility that is part of a multiunit chain, to develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. Regulations at § 483.75(a)(1) through (4) specify that facilities must maintain documentation and demonstrate

evidence of its QAPI program; must present the initial QAPI plan to the State Survey Agency no later than 1 year following the promulgation of the October 2016 final rule (November 28, 2017); must present the QAPI plan at each annual recertification survey and upon request during any other survey and to CMS upon request, and lastly must present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with the program requirements to a State Survey Agency, federal surveyor, or CMS upon request.

In response to the FY 2018 SNF PPS proposed rule comment solicitation, some commenters indicated that for a QAPI program to meet its true intent and be successful, QAPI-related documents should remain confidential in all surveys. Commenters indicated that they have concerns regarding how the QAPI documents will be used during facility surveys and one commenter noted that QAPI-based citations in recent surveys have been used as a ''gotcha'' citation instead of focusing on true quality outcomes. Commenters noted that requiring facilities to disclose their QAPI-related documents limits a facility's ability to identify and prioritize what they believe is important and instead requires them to monitor everything all the time.

We are retaining the existing requirements at § 483.75(a)(1) through (4) because we believe that these requirements are necessary for facilities to demonstrate compliance and to ensure that a facility's QAPI program is ongoing. As part of our certification and enforcement efforts, we have a responsibility to determine compliance through the use of evidence provided by facilities to support compliance decisions. Therefore, we note that to avoid the risk of facility noncompliance, facilities must be able to provide satisfactory evidence that demonstrates compliance with the requirements. Furthermore, we expect that any review of QAPI related documents would occur at the end of the survey, after completion of investigation into all other requirements to ensure that concerns are identified by the survey team independent of the QAPI document review. We encourage readers to refer to the interpretive guidelines for the October 2016 final rule for a full discussion regarding disclosure of information and good faith attempts (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf*).

We are proposing revisions to § 483.75(b), (c), and (d) that would remove the subparagraphs found in each section. Specifically, regulations at § 483.75(b) sets forth parameters for a facility's QAPI program design and scope. We propose to maintain only the introductory text at § 483.75(b), which requires that the QAPI program be ongoing, comprehensive, and address the full range of care and services provided by the facility, and to remove the detailed requirements at § 483.75(b)(1) through (4).

Regulations at § 483.75(c) set forth specific requirements for program feedback, data systems and monitoring. We propose to maintain only the introductory text at § 483.75(c), which requires that facilities establish and implement written policies and procedures for feedback, data collection systems, and monitoring, including adverse event monitoring, and remove the detailed requirements at § 483.75(c)(1) through (4).

Regulations at § 483.75(d) set forth specific requirements for program systematic analysis and systemic action. We propose to maintain § 483.75(d)(1), which requires facilities to 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, and remove the detailed requirements for policies at § 483.75(d)(2).

We believe that these proposed revisions recognize the diversity throughout LTC facilities and would reduce burden on facilities by allowing facilities greater flexibility in tailoring their QAPI programs to the specific needs of the facility. In addition, the proposed requirements for the QAPI program would be consistent with the QAPI requirements for other Medicare and Medicaid participating providers, such as hospitals and other major inpatient provider types.

10. Infection Control (§ 483.80)

Section 483.80 requires LTC facilities to, among other things, establish and maintain an infection prevention and control program (IPCP) designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. Each facility must conduct an annual review of its IPCP and update its program, as necessary (§ 483.80(f)).

Currently, each facility must designate one or more individual(s) as infection preventionists (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; and, (4) have completed specialized training in infection prevention and control. The IP must also be a member of the facility's quality assessment and assurance committee.

Some commenters expressed concern about the burden to providers in complying with these requirements, especially the requirements regarding the IPs. However, we received feedback about how important the new requirements are to improving infection prevention and control in LTC facilities. Infection is the leading cause of morbidity and mortality among the 1.7 million residents of United States nursing homes. Between 1.6 and 3.8 million infections occur each year in these nursing homes, with almost 388,000 deaths attributed to these infections. Significant costs are associated with infections in nursing homes, with estimates ranging from $673 million to $2 billion. An average of 15 percent of nursing homes from 2000 to 2007 received a deficiency citation regarding the infection control requirements (''Nursing home deficiency citations for infection control,'' Am J Infect Control. 2011 May; 39(4): 263–9). Most of these citations were at the D level, which means that they were isolated cases but represented a potential to do more than minimal harm. The infection prevention and control requirements must recognize the serious risks from infectious organisms in LTC facilities without imposing excessive administrative burden on these facilities that will not provide any commensurate improvement in the quality of care provided to residents. Based upon these facts and the feedback we have received regarding the importance of the infection prevention and control requirements in the LTC facility requirements, we believe that the requirements in the 2016 final rule should be retained. However, we are proposing one change to these requirements.

We believe it is essential that the facility's IP(s) have sufficient time to devote to the IPCP to ensure that he or she can achieve the objectives set forth in the facility's IPCP. As set forth in § 483.80(a)(1), the facility must use the facility assessment conducted according to § 483.70(e) in developing its IPCP. Thus, the time necessary for an IP to devote to the facility's IPCP will vary between facilities. Currently, § 483.80(B)(3) requires the IP to work at least part-time at the facility. Part-time could be interpreted in various ways

and could result in confusion. In addition, depending upon the facility's IPCP, IPs might need to devote only a few hours to the IPCP or it might take one or more IPs full-time. Therefore, we are proposing to remove the requirement that the IP work at the facility ''at least part-time'' and insert that the IP must have sufficient time at the facility to meet the objective's set forth in the facility's IPCP. We believe this is an appropriate standard. However, we are also concerned that there could be a substantial variance in how LTC facilities interpret this requirement. Therefore, we are soliciting comments on how should it be determined that the IP has sufficient time to devote to the IPCP to ensure that he or she can achieve the objectives set forth in the facility's IPCP. Please be specific.

11. Compliance and Ethics Program (§ 483.85)

Section 483.85(d)(1)—Additional required components for operating organizations with five or more facilities; 483.85(e)—Annual review; Compliance and ethics—§ 483.95(f)(2).

Section 1128I of the Act requires the operating organizations for SNFs and NFs to have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care consistent with regulations developed by the Secretary. In the final rule published on October 4, 2016, we finalized this requirement along with additional training and personnel requirement that were not expressly required in the statute. However, after a review of these requirements, we are proposing to reduce a majority of the burden currently required under the compliance and ethics program that are not required in the statute because we believe that the SNF and NF CoPs would have the appropriate safety and quality standards to support the compliance and ethics requirements with the proposed changes. Thus we propose to remove the following requirements:

- We propose to remove the requirement that each facility designate a compliance officer and a designated compliance liaison for operating organizations with five or more facilities. Instead, we would propose that such organizations develop a compliance and ethics program that is appropriate for the complexity of the organization and its facilities and that each facility assign a specific individual within the high-level personnel of the operating organization with the overall responsibility to oversee compliance.
- Based on feedback from the industry and stakeholders that the frequency requirement is overly burdensome, we propose to remove the annual review requirement and propose that each organization undertake a periodic assessment of its compliance program to identify any necessary changes. This proposed change would conform to the statutory requirement.
- We propose to eliminate the requirement for a ''compliance and ethics program contact person'' to which individuals may report suspected violations. However, we maintain that is important for individuals to report suspected violations, we will not specify the staff person for this task. Facilities must have a process to accomplish this and we don't want to dictate who they should hire to comply with this requirement. We will maintain the requirement that facilities should have an alternate method of reporting suspected violations anonymously. We would expect the facility to have sufficient resources and designate an individual that would have the appropriate authority to assure compliance with the requirements.
- We propose that the operating organization for each facility develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, established written compliance and ethics standards, policies, and procedures that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act.

We also propose that specific high-level personnel of the operating organization be assigned the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures. We propose to remove the statement in the regulation at § 483.85(c)(2) that states ''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 could be assigned to oversee compliance.'' We are proposing to remove this prescriptive language and would, instead, hold facilities responsible for the effective operation of its program. For additional guidance, we note that the Department of Health and Human Services' Office of the Inspector General (OIG) has issued industry-specific guidance documents in the March 16, 2000 **Federal Register** (65 FR 14289) entitled ''Publication Of The OIG Compliance Program Guidance For Nursing Facilities'', and in the September 30, 2008 **Federal Register** (73 FR 56832) ''OIG Supplemental Compliance Program Guidance For Nursing Facilities.'' The guidance reiterates the basic elements of a compliance and ethics program. It should be the responsibility of the facility to designate an appropriate person to be responsible for all aspects of the compliance and ethics program.

We would expect that the facility would give designated individuals sufficient resources and authority to reasonably assure compliance with the program's standards, policies, and procedures. The facility should not delegate substantial discretionary authority to individuals whom the operating organization knows (or should have known through the exercise of due diligence) had a propensity to engage in criminal, civil, and administrative violations under the Act.

We propose that the facility 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 would include, but are not limited to, mandatory participation in training as set forth in § 483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program. Also, the facility should take reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps would include, but not be 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 within the operating organization without fear of retribution.

The compliance and ethics program contact identified in the operating organization's compliance and ethics program would be required to ensure 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.

After a violation is detected, the operating organization would have to ensure that all reasonable steps

identified in its program were 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.

In addition to the listed requirements, operating organizations that operate five or more facilities and facilities with corporate level management of multi-unit nursing home chains would have to:

- Have a more formal program that included established written policies defining the standards and procedures to be followed by its employees.
- Develop a compliance and ethics program that was appropriate for the complexity of the operating organization and its facilities.

We are proposing to revise § 483.85(e) to require the operating organization for each facility to periodically review and revise its compliance program to identify necessary changes within the organization and its facilities.

12. Physical Environment (§ 483.90)

a. Life Safety Code

On May 4, 2016, we published a final rule, ''Medicare and Medicaid; Fire Safety Requirements for Certain Health Care Facilities,'' adopting the 2012 edition of the National Fire Protection Association (NFPA) 101 (81 FR 26871), also known as the Life Safety Code (LSC). One of the mandatory references in the LSC is NFPA 101A, Guide on Alternative Approaches to Life Safety, also known as the Fire Safety Equivalency System (FSES). On December 16, 2016, CMS issued a survey & certification memo (S & C 17–15–LSC) updating to the newer edition of the NFPA 101A FSES. However, when we updated to the newer FSES that is part of the recently adopted 2012 LSC, some LTC facilities that utilized the FSES in order to determine compliance with the containment, extinguishment and people movement requirements of the LSC were no longer able to achieve a passing score, on the FSES, because of the change in scoring. When adopting the 2012 edition of the LSC and its FSES scoring values we did not anticipate this outcome. Additionally, during the public comment period for the proposed rule (79 FR 21551) we did not receive any public comments to indicate that this would be problematic for certain LTC facilities. Some existing LTC facilities were previously built with wood frame or unprotected steel construction with less than 2 hours of fire rated protection and are 3 or more stories in height. These facilities are fully sprinklered in order to meet both the LTC regulations at § 483.90(a)(6), and the LSC requirements. However, in order to score high enough to meet the FSES standards that are part of the 2012 edition of the LSC, these particular facilities would have to improve their construction type to one that is at least 2 hours of fire rated protection. Changing the construction type from being less than 2 hours of fire rated protection to being at least 2 hours of fire rated protection is extremely burdensome because such construction would completely disrupt the operation of the facility for a substantial period of time. In addition to the quality of care impacts and the financial impacts of service disruptions upon affected facilities in the form of lost revenues of such service disruptions, the significant cost of completing such construction, which we estimate to be $4.75 million per typical affected LTC facility, is likely to result in some permanent facility closures. We believe this would create access to care problems for affected residents and their surrounding communities, in addition to financial hardships for facility owners and staff. In light of the fact that we were not aware of this problem ahead of time, we did not allow for a regulatory phase-in period. However, the S & C 17–15–LSC memo from December 16, 2016 does allow for facilities to have immediate relief by applying for a time-limited waiver of up to 5 years while we pursue a long-term solution. We believe that there is a need for regulatory relief.

In order to address this need, we propose to allow those existing LTC facilities (those that were Medicare or Medicaid certified before July 5, 2016) that have previously used the FSES to determine equivalent fire protection levels, to continue to use the 2001 FSES mandatory values when determining compliance for containment, extinguishment and people movement requirements. Allowing the use of the 2001 FSES scoring values would continue to provide the same amount of safety for residents and staff as has been provided since we began implementing the 2001 FSES in 2003. This would allow existing LTC facilities that previously met the FSES requirements to continue to do so without incurring great expense to change construction type. Based on a review by the states and regional offices, we estimate that there are 50 existing LTC facilities that would no longer be able to achieve a passing score on the new FSES requirements. This is an estimate based on feedback from facilities, states, and CMS Regional Offices. We are proposing to use the following mandatory scoring values:

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.

We would set out this table at § 483.90(a)(1)(iii).

b. Resident Rooms and Bathrooms

The physical environment of a nursing facility is integral to the resident's health and safety. Therefore, the facility must be designed, constructed, equipped, and maintained to protect the health and safety of

residents, personnel, and the public. The October 2016 final rule implemented new physical environment requirements at § 483.90 related to space and accommodations within facilities. Specifically, regulations at § 483.90(e)(1)(i) require newly constructed, re-constructed, or facilities first certified after November 28, 2016 (the effective of Phase One of the October 2016 final rule) to accommodate no more than two residents in a bedroom. Regulations at § 483.90(f) require newly constructed and facilities first certified after November 28, 2016 to equip each resident room with its own bathroom that has a commode and sink.

The October 2016 final rule responded to commenters' concerns that the proposed rule was too burdensome; however, industry stakeholders have continued to share concerns regarding the burden associated with these requirements, specifically noting that the requirements discourage building, remodeling, upgrading, and the purchasing of facilities. We recognize these concerns and unintended consequences. However, we continue to believe that the finalized physical environment requirements address valid health and safety concerns. Specifically, we believe that more than two residents to a room not only infringes on a resident's privacy and dignity, but also creates issues related to infection control and resident safety. Likewise, we believe that rooms without bathrooms increase risks related to falls, quality of care, and infection control.

Therefore, we are not proposing to entirely remove these requirements. We are proposing to revise § 483.90(e)(1)(i) regarding the number of residents per room and § 483.90(f) regarding bathroom facilities, to apply only to newly constructed facilities and newly certified facilities that have never previously been a long-term care facility. We believe that these revisions would reduce burden by removing any unintended disincentives to purchase or upgrade existing facilities, while ensuring that any new facilities (either newly constructed or converted into a nursing home) are properly equipped to accommodate residents in a reasonable and safe manner. However, we note that when purchasing or updating facilities, this may create an opportune time to update facility rooms and bathrooms in an effort to address infection risks and quality of life concerns. For example, when providing care for residents during a norovirus outbreak, having sinks in resident rooms would allow staff easier access to wash their hands and conduct effective infection prevention and control practices to avoid further contamination. Therefore, we are soliciting comments as to whether it would be appropriate to sunset the exception we propose to provide for buildings that were previously long-term care facilities. If so, what would be a reasonable time frame for sunsetting this exemption to balance the needs of residents for privacy, quality of life, and infection prevention and the desire to maintain access to facilities and avoid the unintended consequences discussed previously.

13. Technical Corrections

Admission, Transfer, and Discharge Rights § 483.15

Section 483.15 includes an incorrect cross-reference. Specifically, § 483.15(c)(1)(ii) includes an incorrect cross-reference to § 431.220(a)(3). We propose to revise § 483.15(c)(1)(ii) to correct the cross reference by replacing ''§ 431.220(a)(3)'' with ''§ 431.220(a)(2)''.

Nursing Services § 483.35

Section 483.35 includes incorrect cross-references. Specifically, § 483.35(a)(2) and § 483.35(e)(4) include incorrect cross-references to paragraph (c) of this section. In addition, § 483.35(f)(2) includes an incorrect cross-reference to paragraph (d)(1) of this section. We propose to revise § 483.35 to correct the cross references by replacing ''paragraph (c)'' with ''paragraph (e)'' in § 483.35(a)(2) and (e)(4) and replacing ''paragraph (d)(1)'' with ''paragraph (f)(1)'' in § 483.35(f)(2).

Physical Environment § 483.90(d)

On July 13, 2017, we issued a correcting amendment, ''Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities'' (82 FR 32256) to correct technical and typographical errors identified in the October 4, 2016 final rule. This document inadvertently removed revisions made to § 483.90(d), which were finalized in the October 2016 final rule. Specifically, the October 2016 rule finalized requirements at § 483.90(d) (incorrectly labeled paragraph (c) in the October 2016 final rule) for facilities to—(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 at § 483.90(d)(1)); (2) maintain all mechanical, electrical, and patient care equipment in safe operating condition at § 483.90(d)(2); and (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 at § 483.90(d)(3).

We discussed the revisions in § 483.90(d) in the October 2016 final rule, responded to public comments related to this issue, and concluded that we were finalizing the requirement (see 81 FR 68817). Therefore, we are proposing to correct the error in the Code of Federal Register to revise § 483.90(d)(1) and to add § 483.90(d)(3).

Diagnostic X Ray Tests, Diagnostic Laboratory Tests, and Other Diagnostic Tests: Condition (§ 410.32)

Section 410.32 includes an incorrect cross-reference to Part 483. Specifically, § 410.32(d)(1)(vii) includes an incorrect cross-reference to § 483.75(k)(1)(i). We propose to revise § 410.32(d)(1)(vii) to correct the cross reference by replacing ''§ 483.75(k)(1)(i)'' with ''§ 483.50(a)(1)(i)''.

B. Survey, Certification, and Enforcement Procedures

1. Informal Dispute Resolution (IDR) (§ 488.331) and Independent Informal Dispute Resolution (§ 488.431)

To assess compliance with the LTC requirements, surveyors conduct onsite inspections (surveys) of facilities. In the survey process, surveyors directly observe the actual provision of care and services to residents and the effect or possible effects of that care to assess whether the care provided meets the assessed needs of individual residents.

Among the statutory enforcement remedies available to the Secretary and the states to address facility noncompliance are CMPs, authorized by sections 1819(h) and 1919(h) of the Act. CMPs may be imposed for each day or each instance of facility noncompliance, as well as for past instances of noncompliance even if a facility is in compliance at the time of the current survey. The regulations that govern the enforcement remedies authorized by the statute, were published in the **Federal Register** on November 10, 1994 (59 FR 56116).

Facilities that are dissatisfied with a certification of noncompliance have an informal opportunity, if they request it, to dispute cited deficiencies upon receipt of the official statement of deficiencies. For surveys conducted pursuant to section 1864 of the Act, this informal dispute resolution (IDR)

process is provided by the state. The requirement for IDR is specified at § 488.331. Policy guidance in section 7212 of CMS's *State Operations Manual* (Pub. 100–07) (SOM) specifies the mandatory elements that must be included in each State's IDR process. There is no specification for how long the IDR process should take to be completed. We are proposing to add language to specify that IDR would be completed within 60 days of the facility's request to dispute the survey findings if the request by the facility is timely. This is consistent with the time frame for the completion of an Independent IDR.

NFs and dually-participating SNF/NFs are provided the opportunity to request and participate in an Independent IDR if CMS imposes CMPs against the facility. The requirement for Independent IDR is specified at § 488.331. Policy guidance in section 7213 of CMS's SOM specifies the mandatory elements that must be included in each State's Independent IDR process. Current guidance in the SOM at 7212.3 and 7213.9 specify that the results of a survey should not be uploaded to the Certification and Survey Provider Enhanced Reports (CASPER) system before the resolution of the IDR or the Independent IDR. We are proposing to add this language in regulation as we have been made aware that these instructions are not always being followed; and entering the survey results before the dispute processes have been completed may negatively affect a facility's Five Star quality rating on Nursing Home Compare.

Current guidance in the SOM at 7213.6 specifies the qualifications of an approved Independent IDR reviewer (entity or person). One of the qualifications is a specific understanding of Medicare and Medicaid program requirements. While this is specified in regulation regarding an independent entity, it is not specified in the example given of a component of an umbrella State agency that is separate from the SA. In order to clarify that this is indeed a requirement for the component, we are proposing to add language to the regulation.

Note: State health agencies are either independent agencies or a unit of a larger agency, often referred to as an umbrella agency.

Finally, as outlined in current sub-regulatory guidance when an outside entity conducts the Independent IDR process based on the results of a state-conducted or federally-conducted survey, the results serve only as a recommendation of noncompliance or compliance to the State or CMS. If the State or CMS disagrees with the Independent IDR recommendation, the written record provided to the facility will contain the result of each deficiency challenged and a summary of the rationale for that result so that the facility understands the Independent IDR panel's recommendation and why the State or CMS do not agree with that recommendation.

Current SOM guidance provides instruction regarding what should be provided to the facilities as part of the written record but CMS has been made aware that the facility is sometimes only receiving the final decision and no rationale is included for the decision, which leads to confusion as to why an Independent IDR recommendation is not followed. We are proposing to add this language in regulation to strengthen this requirement.

Based on stakeholder input, we propose that additional language be added to the CMS enforcement regulations at § 488.331 and § 488.431 to clarify and strengthen regulations and provide more specific requirements to states and CMS regarding both the IDR process and the Independent IDR processes. We would—(1) specify that an IDR process must be completed within the same timeframe that we specify for the Independent IDR process; (2) provide states with more specific instructions on when the results of a survey should be transferred for inclusion in the national reporting system; (3) clarify the knowledge required by an approved independent entity; and (4) specify that the final result of an Independent IDR (including the rationale behind the decision) must be relayed to a facility by either the state or CMS in writing. We discuss these proposed revisions and invite public comment on the proposed changes.

We proposed to revise § 488.331(b)(1) by adding new language to specify that the IDR process shall be completed within 60 days of the facility's request to dispute the survey findings if the request by the facility is timely. In order to reduce confusion and ensure consistency between the IDR and Independent IDR processes, we are requiring the same time frame for completion for both processes. In the case where a CMP is imposed, facilities disputing the survey results are still required to pay the CMP and it is held in an escrow account until a final administrative decision has been made. Specifying the time frame for the completion of the IDR process will potentially reduce burden on facilities who will have the money returned to them sooner when they are successful in their appeal.

At proposed § 488.331(b)(2), we propose to add specific instructions to states explaining when survey results should be uploaded into the CASPER system. These survey results are used to calculate a facility's Five-Star quality rating on the Nursing Home Compare website and are not to be uploaded into CASPER before the resolution of the IDR or Independent IDR processes. This specification will provide consistency to the upload process and prevent survey results from being uploaded prior to completion of the dispute process. Recognizing that the public as well as other organizations, use Nursing Home Compare to assist in decision-making about residing or contracting with a specific facility, this will reduce burden on providers by ensuring that the CMS website contains accurate survey information that includes any post-survey review through the IDR or Independent IDR process. It would also reduce burden on states by minimizing the amount of corrections and changes to data that would need to be made if information were uploaded prematurely.

At § 488.431(a)(2), we propose to add new language to specify that the facility must receive written notification of the results of the Independent IDR, including the rationale for the final decision. The rationale must be provided by CMS or the states depending upon who made the final determination. Although SOM guidance instructs states and CMS to send written notification of the Independent IDR recommendation to the facility, there may be times when the state or CMS disagrees with the Independent IDR entity's recommendation and it is not accepted as the final decision. In this case, the rationale for the disagreement must be documented by CMS or the state as part of their normal process and provided to the facility to ensure clarity in why a final decision was made that differs from the Independent IDR's recommendation. This would reduce burden on facilities as, adding this to regulation, they would be made aware of the availability of this information and would not have to spend time trying to figure out the process for requesting an explanation of the final decision.

At § 488.431(a)(4)(i), we propose to add language to clarify that, in order to be approved to conduct an Independent IDR, a component of an umbrella state agency must have a specific understanding of Medicare and Medicaid program requirements. Although this information is provided in guidance, including it in regulation will strengthen this provision. In

addition, it will reduce burden by decreasing the possibility of providers having to dispute the qualifications of the entity chosen to conduct the Independent IDR process and/or its recommendations.

2. Civil Money Penalties: Waiver of Hearing, Reduction of Penalty Amount (§ 488.436)

Requirements at § 488.436 regarding the option for a facility to waive hearing rights and receive a 35 percent reduction in the amount of CMPs owed were first adopted in a 1994 final rule (59 FR 56116–01), with minor corrections to the text in 1997 (62 FR 44221). Over the years, we have observed that most facilities facing CMPs do not request a hearing to appeal the survey findings of noncompliance on which their CMPs are based. In CY 2016, 81 percent of LTC facilities submitted a written waiver of the hearing and an additional 15 percent of facilities failed to submit a waiver although they did not contest the penalty and its basis. Only 4 percent of facilities availed themselves of the full hearing process. Therefore, based on our experience with LTC facilities facing CMPs and the input provided by CMS Regional Offices who impose and collect CMPs, we propose to revise these requirements at § 488.436 by creating a constructive waiver process that would produce the same, or better, results for less money and effort.

Specifically, we propose to revise the current express waiver process to one that seamlessly flows to a constructive waiver and retains the accompanying 35 percent penalty reduction. This would result in lower costs for most LTC facilities facing CMPs and would streamline and reduce the administrative burden for all stakeholders.

We propose to amend the language at § 488.436(a), by eliminating the requirement to file a written waiver and create in its place a constructive waiver process that would operate by default when CMS has not received a timely request for a hearing. Facilities that wish to request a hearing would continue to follow all other appeals process requirements, including those at § 498.40, as currently referenced in part 488 at § 488.431(d).

We propose language at § 488.436(a) stating that a facility is deemed to have waived its rights to a hearing if the time period for requesting a hearing has expired and CMS has not received a timely request for a hearing. For the 81 percent of LTC facilities that submit a written hearing waiver and receive a 35 percent reduction in the amount of their CMPs, these facilities must then pay the amount due (minus the 35 percent reduction). We have observed that many facilities submitting a request for a waiver of hearing wait until close to the end of the 60-day timeframe within which a waiver must be submitted, thus delaying the ultimate due date of the CMP amount. For these reasons, we believe the constructive waiver process would meet the needs of most facilities facing CMPs.

We believe that other circumstances can be addressed under § 488.444, whereby CMS has authority to settle CMP cases at 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 § 488.30. We believe that eliminating the current requirements at § 488.436 for a written waiver will not negatively impact facilities, and as such, we especially welcome comments from the public addressing any potential circumstances in which facilities' needs could best be met or only be met by the use of an express, written waiver.

In addition to the changes to § 488.436(a), we propose corresponding changes to § 488.432 and § 488.442 which now reference only the written waiver process. Finally, we note that the current requirements at § 488.436(b) would remain unchanged.

3. Phase 3 Implementation of Overlapping Regulatory Provision

The revised LTC requirements for participation are being implemented in three phases. Phases 1 and 2 were implemented in November of 2016 and 2017 respectively. Phase 3 includes additional regulatory provisions that are scheduled to be implemented on November 28, 2019. Each phase requires a significant level of activities, including interpretive guidance drafting and publication, provider education, software development, and surveyor training.

Of the Phase 3 provisions, this regulation proposes revisions that, if finalized, would have an impact on provisions that fall into three primary areas—(1) designation and training of the infection preventionist (§ 483.80), Quality Assurance and Performance Improvement (QAPI) (§ 483.75), and compliance and ethics program (§ 483.85). We list the specific regulatory citations in table 2 that follows.

Table 2. Impacted Phase 3 Regulatory Provisions

Current CFR Citation	Subject
483.75(a)(1), (4),	Quality Assurance and Performance Improvement
(b)(1)-(4)	Program Design and Scope
(c)(1)-(4),	Program Feedback, Data Systems, and Monitoring
(d)(1)-(2),	Program Systematic Analysis and Systematic Action
(e)(1)-(3),	Program Activities
(f)(1)-(6), and	Governance and Leadership
(g)(1)(iv), (g) (2)(iii)	Quality Assessment and Assurance
483.80(b)(1)-(4),(c)	Infection Preventionist Qualifications/Specialized Training
483.85(a)-(e)	Compliance and Ethics Program
483.95(d)	QAPI Training
483.95(f)(1)(2)	Compliance and Ethics Training

We are proposing to delay implementation of the above regulatory sections except for the requirements related to the Infection Preventionist at § 483.80(b)(1) through (4) and (c) and § 483.75(g)(1)(iv) (participation of Infection Preventionist on the quality assessment and assurance committee). We do not propose to delay the implementation of the infection preventionist requirements because the reduction in burden is related to the time required onsite. The requirements related to the infection preventionist's required training and role remain unchanged, and we therefore believe this requirement can be implemented as scheduled. For those requirements that we propose to delay implementation, we propose to implement them one year after the effective date of the finalization of this rule.

The purpose of this delay is to avoid unnecessary work, confusion and burden associated with implementing provisions that are proposed to be changed in this rule. We understand potential concerns regarding further delaying the implementation of the QAPI and compliance and ethics requirements, as these provisions were required to be implemented by statute in 2012 and 2013 respectively. However, we believe that moving forward with implementing these provisions in November 2019, only to implement significant revisions to the provisions proposed in this rule, would create significant additional work and confusion for the nursing home community. In addition, this would create administrative burden to Regions and States in software changes and surveyor re-training.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In analyzing information collection costs, we rely heavily on wage and salary information. Unless otherwise indicated, we obtained all salary information from the May 2017 National Occupational Employment and Wage Estimates, United States by the Bureau

of Labor Statistics (BLS) at *https://www.bls.gov/oes/current/oes_nat.htm.* Furthermore, where applicable, the wage information for each occupation were pulled from the BLS industry category ''nursing care facilities (skilled nursing facilities). Based on this information, we have calculated the estimated hourly rates in this proposed rule based upon the national mean salary for that particular position increased by 100 percent to account for overhead costs and fringe benefits. The raw wage and salary data from the BLS do not include health, retirement, and other fringe benefits, or the rent, utilities, information technology, administrative, and other types of overhead costs supporting each employee. HHS department-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation to these overhead and fringe benefit costs.

The table that follows presents the BLS occupation code and title, the associated LTC facility staff position in this regulation, the estimated average hourly wage, and the adjusted hourly wage (with a 100 percent markup of the salary to include fringe benefits and overhead costs).

Table 3. Summary Information of Estimated Hourly Cost

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
29-1141	Registered Nurses	Registered Nurse	$31.59	$63
29-2061	Licensed Practical or Vocational Nurse	Licensed Nurse	$22.61	$45
11-9111	Medical and Health Services Managers	Director of Nursing	$44.59	$89
11-9111	Medical and Health Services Managers	Administrator	$44.59	$89
21-1022	Healthcare Social Workers	Social Worker	$24.48	$48
43-9061	Office Clerks, General	Office Assistant	$15.71	$31
29-1062	Family and General Practitioners	Physician	$95.54	$191
23-1011	Lawyer	Attorney	$68.22	$136
31-1014	Nursing Assistant	Nurse Aide	$13.20	$26
11-9051	Food Service Manager	Director of Food and Nutrition Services	$29.97	$60
29-1031	Dietitian	Dietitian	$27.98	$56
37-1010	First-line Supervisor of Building and Grounds and Maintenance Worker	Facility Manager	$19.24	$38

This proposed rule does not impose any new information collection, recordkeeping or third-party disclosure requirements. However, this proposed rule would create certain savings related to information collection, recordkeeping or third-party disclosure requirements. While we detail all of the estimated savings of this proposed rule in the regulatory impact analysis, this section provides a brief summary of the estimated savings associated with the information collection request (ICR) for LTC requirements (0938–1363) which will be sent to OMB for review. We are soliciting public comment on each of these issues for the following sections of this document that contain ICRs.

Requirements for Participation

1. ICRs Regarding Resident Rights (§ 483.10)

We propose several revisions to the regulations at § 483.10(j) that require facilities to develop a grievance policy. Proposed revisions include removing duplicative requirements, clarifying that everyday feedback may not rise to the level of an official grievance, removing

the requirement for facilities to designate a grievance official, remove prescriptive requirements related to written grievance decisions, and reducing the requirement for facilities to retain evidence demonstrating the results of grievances from 3 years to 18 months. Based on these proposals, we believe that there may be minor information collection cost reductions for developing a grievance policy. However, we believe that the majority of the cost savings are included in the proposal to remove the requirement for the grievance official to oversee the grievance process. We discuss these cost savings in the Regulatory Impact Analysis section.

2. ICRs Regarding Freedom, Abuse, Neglect, and Exploitation (§ 483.12)

The proposed revisions to the reporting requirements for abuse provide flexibility around the timeframes for reporting, but do not eliminate any of the reporting requirements. Therefore, while we believe the proposed revisions address stakeholder concerns and provide flexibility, the proposed revisions will have negligible effects on information collection costs.

3. ICRs Regarding Admission, Transfer, and Discharge Rights (§ 483.15)

We propose to revise the requirement for facilities to send copies of transfer or discharge notices to the Office of the State Long-Term Care Ombudsman to apply specifically to involuntary transfers or discharges only. In the October 2016 final rule we indicated that this cost would apply primarily to residents who are involuntarily discharged from the facility and does not include residents who request the transfer or who are transferred on an emergency basis to an acute care facility. Based on these assumptions, we estimated that the requirement would apply to one third of all LTC facility residents resulting in a cost of $1,340,936 related to make a copy of the notice, apply postage (if mailed), and the time of an office assistant to prepare and send the notice.

The proposed revisions would clearly establish the expectation that this requirement would apply to involuntary transfers or discharges only. Based on stakeholder comments, while we previously estimated that the requirement would apply to only one third of all LTC residents, many facilities have been sending the notice with all discharges and transfers rather than only involuntary discharges and transfers. Therefore, we estimate that the existing requirement applies to two thirds of all residents resulting in an updated estimated cost of $2,946,095 ($.10 (cost to make a copy per notice) + $.63 (cost for pre-stamped envelope based on USPS retail) + $2.58 (5/60 of an office assistant $31 hourly wage) × 889,163 (⅔ of 1,333,745 LTC residents)). We estimate further that with the proposed revisions, this requirement would apply to one third of all LTC facility residents, resulting in an estimated cost of $1,473,047 ($.10 (cost to make a copy per notice) + $.63 (cost for pre-stamped envelope based on USPS retail) + $2.58 (5/60 of an office assistant $31 hourly wage) × 444,582 (⅓ of 1,333,745 LTC residents)). Therefore, the cost savings to facilities would be the difference between sending notices related to all transfers and discharges versus involuntary transfers and discharges only, resulting in a total cost savings of $1,473,047 ($2,946,095 − $1,473,047).

4. ICRs Regarding Nursing Services (§ 483.35)

The proposed revisions in this section are related to record retention. While we believe that reducing the timeframe for maintaining records will produce cost savings to facilities, there are no collection of information requirements associated with this proposed change because maintaining records in this instance is considered a usual and customary practice in accordance with the implementing of regulations of the PRA 5 CFR 1320.3(b)(2).

5. ICRs Regarding Administration (§ 483.70(e))

LTC facilities are required to address in the facility assessment the facility's resident population (that is, number of residents, overall types of care and staff competencies required by the residents, and cultural aspects) and equipment. We estimate that it takes a facility 20 hours annually to conduct and document a facility-wide assessment. As stated previously, the facility must utilize information collected under the requirements stated under this section and the information collection required under §§ 483.35, 483.40(a), 483.60(a), and 483.75. We estimate that it requires an administrator 8 hours to collect and analyze data from throughout the facility; 6 hours for the director of nursing to collect and analyze staffing data; 2 hours for an office assistant to collect and document data; and 2 hours each for a facility manager and a physician to review and provide input. We are proposing to reduce burden on facilities by changing the annual facility assessment requirement to a biennial requirement. We estimate that the burden would be reduced as follows: An administrator, at the hourly wage of $89 an hour × 8 = $712; director of nursing wage of $89 an hour × 6 hours = $534; office assistant wage of $31 an hour × 2 hours = $62; physician $191 an hour × 2 = $382; facility manager $38 an hour × 2 = $76. The total cost per facility is $1,766. We estimate a total burden reduction of 20 hours and $27.6 million in a 2-year period (15,639 SNFs/NFs × $1,770 per facility = $27,618,474). Since this savings occurs biennially, the annual savings is one-half of this, or $13,809,237.

6. ICRs Regarding Quality Assurance and Performance Improvement Program (§ 483.75)

Regulations at § 483.75 require facilities to develop, implement, and maintain an effective, comprehensive, data-driven QAPI program. The existing information collection assumes that it would take appropriately 56 burden hours for a facility to develop and document a QAPI program designed to monitor and evaluate performance of all services and programs of the facility. We maintain this assumption. Based on 2017 BLS data, the estimated cost to comply with the QAPI requirements is $5,016 per facility (the facility administrator (30 hours × $89 = $2,670); the director of nursing (10 hours × $89 = $890); a registered nurse (10 hours × $63 = $630); a physician (4 hours × $191 = $764); and an office assistant (2 hours × $31 = $62). The total cost for 15,639 LTC facilities is an estimated $78,445,224.

This rule proposes to revise the requirements in § 483.75 to provide facilities with the flexibility needed to tailor their QAPI programs to the individual needs of their specific facility. Specifically, we have proposed to remove the prescriptive requirements at § 483.75(b)(1) through (4), and § 483.75(c)(1) through (4), and all of the requirements in § 483.75(d)(2). A detailed discussion of the proposed removal of these requirements can be found in section II.A.

The proposed removal of these prescriptive requirements would focus the QAPI requirements on the expected results of the program and would no longer prescribe the structures and methods for implementing the QAPI program. This provides flexibility to the facility, as it is free to develop a creative program that meets the needs of the facility and reflects the scope of its services and operations. Given the flexibility provided by the revisions and the variability across facilities as to where they are in the current efforts for developing a QAPI program, we believe

the expected savings that these flexibilities would provide to each individual facility is difficult to predict. However, we do expect that the added flexibilities would result in a reduction of the burden hours necessary to comply with these requirements.

Therefore, we assume that the current time and effort necessary to develop initial internal policies that reflect the individual goals set by the facility of 56 burden hours could be reduced by half. This would result in a cost of $2,508 per facility (the facility administrator (15 hours × $89 = $1,335); the director of nursing (5 hours × $89 = $445); a registered nurse (5 hours × $63 = $315); a physician (2 hours × $191 = $382); and an office assistant (1 hours × $31 = $31). The total cost for 15,639 LTC facilities is an estimated $39,222,612. Therefore, this would result in a burden reduction of 28 hours and $39,222,612 from the current requirement. This is a reduction in total burden hours of 437,892 (875,784 − 437,892). For purposes of this estimate, we assume that facilities have not incurred the full one-time cost to meet the existing requirement for initial policy development (due to be implemented November 2019), and that the amended requirement will not affect the annual implementation costs. We solicit public comment on our assumptions, and whether commenters believe there could be additional costs or savings that we have not included in this estimate, as well as on the accuracy of our savings estimate.

7. ICRs Regarding Compliance and Ethics Program (§ 483.85)

We propose to reduce burden by removing the mandatory annual training requirements for the operating organization's compliance and ethics program. We have proposed that each facility must review its compliance and ethics program biennially and revise its program as needed to 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. In addition, we propose to change the annual review requirement to require operating organizations for each facility to review its compliance and ethics program biennially and revise its program as needed to reflect any changes.

For the purpose of this analysis, we are utilizing the burden rationale that we provided and published in the rule on October 4, 2016 (81 FR 68842). We have made cost updates to reflect current staff costs and number of facilities. We propose to reduce burden on facilities by eliminating the annual training requirement. There are currently about 15,639 SNFs and NFs. We estimate that training staff requires the duties of a RN for 2 hours per facility. The cost for all 15,639 facilities would be $1,970,514 (15,639 × 2 hours × $63 average hourly wage). This is a reduction of 31,278 burden hours. Based on our experience with SNF and NF facilities, we expect that operating organizations that operate 1–5 facilities have been able to minimize training costs by including the training on their compliance and ethics program with any current trainings or in-services that they already conduct for their staff.

Without data to make this assertion, we have made the above calculation apply to all facilities and ask for both data and comments regarding the savings associated with removing this requirement. Facilities would still be required to effectively communicate standards, policies and procedures through a training program or in another practical manner. For example, online or video training modules could be used. However, we are no longer designating the manner nor the frequency for such instruction, nor requiring that facility staff be trained to provide such instruction.

We also propose to reduce burden for § 483.85(e) by changing from an annual review to a biennial review of the compliance an ethics program. We expect that the administrator and director of nursing would annually spend 5 hours each reviewing the program to ensure its compliance. The administrator and director of nursing salaries would total $890 ($178 combined hourly total for the administrator and director of nursing × 5 hours). We estimate a biennial savings of $5,873,110 ($890 × 6,599 operating facilities) and 65,990 hours (6,599 operating facilities × 10 hours). Since this savings occurs biennially, the annual saving is one-half of this, or $2,936,555 and 32,995 hours

The total annualized reduction in information collection cost for these reforms would be an estimated $4,907,069 ($1,970,514 + $2,936,555). The total reduction in burden hours is 64,273 hours.

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by September 16, 2019.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

We periodically review the Medicare and Medicaid health and safety standards in an effort to ensure that they do not unnecessarily burden patient or regulated entities, remain current, and reflect advances in the health care industry. We are proposing revisions to the LTC requirements that would simplify and streamline the current requirements, increase flexibility in LTC facilities, and reduce excessively burdensome requirements, while maintaining a focus on providing high quality care to residents. This proposed rule would also reduce the frequency of certain required activities, revise timeframes for certain requirements where appropriate, and remove obsolete, duplicative, or unnecessary requirements. Ultimately, these proposals balance resident safety and quality of care, while also providing regulatory relief for facilities.

B. Overall Impact

We have examined the impacts of this rule as required by E.O. 12866 on Regulatory Planning and Review (September 30, 1993), E.O. 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), E.O. 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and E.O. 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

E.O. 13771 states that it is essential to manage the costs associated with the government imposition of private expenditures required to comply with federal regulations and establishes policies and procedures to reduce the costs of both new and existing federal regulations. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory

approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of E.O. 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that to the best of our ability presents the costs and benefits of the rulemaking.

In accordance with the provisions of E.O. 12866, this regulation was reviewed by the Office of Management and Budget. This proposed rule contains proposals that would create ongoing cost savings to LTC facilities. Other revisions we have proposed would clarify existing policy and relieve some administrative burdens. The financial savings are summarized in the table that follows. We welcome public comments on all of our burden assumptions and estimates as well as comments identifying additional reforms that should be considered in the final rule or future rulemakings. As discussed later in this regulatory impact analysis, uncertainty surrounds these estimates and we especially solicit comments on either our estimates of likely savings or the specific regulatory revisions that drive these estimates.

C. Sources of Data Used in Estimates of Burden Hours and Cost Estimates

We obtained the data used in this discussion on the number of Medicare and Medicaid participating LTC facilities from Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) as of May 2018, unless indicated otherwise. We have not included data for facilities that are not Medicare or Medicaid certified. As of May 2018, there are 15,639 LTC facilities that participate in the Medicare and/or Medicaid program.

Unless otherwise indicated, we obtained all salary information from the May 2017 National Occupational Employment and Wage Estimates, United States by the BLS at *https://www.bls.gov/oes/current/oes_nat.htm* and we have calculated the estimated hourly rates in this proposed rule based upon the national mean salary for that particular position increased by 100 percent to account for overhead costs and fringe benefits. The raw wage and salary data from the BLS do not include health, retirement, and other fringe benefits, or the rent, utilities, information technology, administrative, and other types of overhead costs supporting each employee. HHS department-wide guidance on preparation of regulatory and paperwork burden estimates states that doubling salary costs is a good approximation to these overhead and fringe benefit costs. The hourly wages calculated on this basis are shown in Table 3 in Section III Collection of Information.

D. Anticipated Effects on LTC Facilities

Table 4 summarizes the expected savings to facilities from the preceding information collection reforms and the other cost savings addressed in detail in the following section of the RIA.

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Table 4. Summary of Cost Reductions*

Regulatory Provisions	Annual IC Savings	Annual Other Savings	Total Annual Savings
A. Requirements for Participation			
1. Resident Rights (§483.10)			
a. Choice of Attending Physician	NA	NA	NA
b. Grievances	NA	$78,069,888	$78,069,888
2. Admission, Transfer, and Discharge Rights (§483.15)	$1,473,047	NA	$1,473,047
3. Quality of Care (§483.25)	NA	NA	NA
4. Nursing Services (§483.35)	NA	NA	NA
5. Behavioral Health (§483.40)	NA	NA	NA
6. Pharmacy Services (§483.45)	NA	NA	NA
7. Food and Nutrition Services (§483.60)	NA	$19,142,136	$19,142,136
8. Administration (§483.70)--Facility Assessment (§483.70(e))	$13,809,237	NA	$13,809,237
9. Quality Assurance and Performance Improvement (§483.75)	$39,222,612	NA	$39,222,612
10. Infection Control (§483.80)	NA	NA	NA
11. Compliance and Ethics Program (§483.85)	$4,907,069	$109,909,488	$114,816,557
12. Physical Environment (§483.90)			
a. Life Safety Code**	NA	$48,000,000	$48,000,000

b. Resident Rooms and Bathrooms	NA	$328,000,000	$328,000,000
B. Survey, Certification, and Enforcement Procedures			
13. Informal Dispute Resolution and Independent Informal Dispute Resolution (§488.331 and §488.431)	NA	NA	NA
14. Civil Money Penalties: Waiver of Hearing, Reduction of Penalty Amount (§488.436)***	NA	$1,233,112	$1,233,112
15. Notification of Intent to Delay Phase 3 Implementation of Overlapping Regulatory Provisions	NA	NA	NA
Totals	$59,411,965	$584,354,624	$643,766,589

* These estimates for the first full year.
** Life Safety Code cost savings of $240 million spread over five years.
*** Approximately $0.7 million of this amount is a transfer related to reduced CMPs imposed on facilities.

1. Resident Rights (§ 483.10(j))

We propose several revisions to the regulations at § 483.10(j) that require facilities to develop a grievance policy. In the October 2016 final rule, we indicated most facilities already have a

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grievance process and therefore, the cost associated with establishing a grievance policy would mainly be attributed to the requirement for a grievance official with specific duties. This rule proposes, at § 483.10(j)(4)(ii), to remove the specific duties required of the grievance official. The October 2016 final rule estimated that the regulatory burden for establishing a designated grievance official to oversee the grievance process and to perform specific duties is $156,139,776 annually (updated to reflect current salary information). The revision would eliminate the staff burden associated with the specific tasks that must be performed by the grievance official. Facilities would have the flexibility to determine how their grievance policy can be tailored to fully address grievances and establish the necessary duties of their designated grievance official.

We assume that removing the prescriptive required duties would reduce the current burden by approximately half due to the increased flexibility that would allow facilities to execute a grievance process in the most efficient manner for each facility's needs. Therefore, this proposal would result in a cost savings of $78,069,888 (5 percent of a social worker FTE × $48 hourly wage for a social worker × 2,080 hours (40 hours a week × 52 weeks) × 15,639 facilities). We request comments on this assumption.

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

The cost savings to facilities for proposals in this section are related to paperwork burden and discussed in detail in the Collection of Information section. We estimate a total cost savings of $1,148,503.

3. Quality of Care (§ 483.25)

The proposed revisions in the section clarify existing requirements related to the use of bedrails and have negligible effects on reducing facility costs.

4. Nursing Services (§ 483.35)

The proposed revisions in this section are related to administrative processes and any cost savings would normally be discussed in the Collection of Information section. However, as noted the proposed revisions in this section are related to record retention. While we believe that reducing the timeframe for maintaining records will produce cost savings to facilities, there are no collection of information requirements associated with this proposed change because maintaining records is considered a usual and customary practice in accordance with the implementing of regulations of the PRA 5 CFR 1320.3(b)(2). Moreover, we believe that the cost savings from the reduced duration of the daily staffing list storage requirement would be minimal, saving at most the equivalent of one file cabinet drawer of space per facility.

5. Behavioral Health (§ 483.40)

The proposed revisions in this section remove duplicative requirements and do not affect facility costs.

6. Pharmacy Services (§ 483.45)

The proposed reforms in this section are aimed to strengthen resident protections by eliminating unnecessary restrictions on prescribers' ability to tailor psychotropic prescriptions to resident needs, avoiding unnecessary delays in prescribing, and placing responsibility on facilities to develop more tailored policies on using PRN orders for psychotropic drugs. We expect that these reforms will reduce unnecessary interruptions in some residents' care while preserving needed resident protections. We do not expect significant changes in either costs or benefits and have not attempted to make a quantitative forecast of either.

7. Food and Nutrition Services (§ 483.60)

We propose to revise the required qualifications for a director of food and nutrition services to provide that those with several years of experience performing as the director of food and nutrition services in a facility can continue to do so. This is a major change from the October 2016 final rule, which added credentialing requirements for the director of food and nutrition services to include being a ''certified food service manager,'' or ''certified dietary manager,'' or ''has similar national certification . . . from a national certifying body,'' or has an associate's or higher degree in food service or restaurant management. Under the October 2016 final rule, a significant fraction of current directors of food and nutrition services would have had to be replaced or, at great expense, have had to attend an institution of higher education to obtain required credential.

The current annual cost for the director of food and nutrition services is an estimated $122,400 annually (updated to reflect current salary information and including fringe benefits and overhead costs). We previously estimated that 10 percent of facilities would need to pursue additional candidates that meet the new qualifications for a director of food and nutrition services. Assuming that, on average, there is a 10 percent wage differential between those with experience but no further credential, and those who would have met the standards of the October 2016 final rule for director of food and nutrition services either as specified in that rule, or by meeting the even higher standards for ''qualified dietician,'' this means that removing those standards would reduce costs to facilities by $19,142,136 (10 percent of 15,639 facilities × $12,240). In this calculation, the wage differential is assumed to be only about 10 percent because there are offsetting costs to the facility for retaining staff who are qualified by experience but who may need expert help, such as the proposed requirement for frequently scheduled consultation with a qualified dietician. We welcome comments on these estimates and additional information that would help us improve them.

We propose that at a minimum an individual designated as the director of food and nutrition services receives frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional; and has 2 or more years of experience in the position of a director of food and nutrition services, or has completed a minimum course of study in food safety. These revisions would provide an experience qualifier that would likely eliminate the need for many facilities to hire additional or higher salaried staff.

8. Administration (483.70)

We discuss the economic impact for the administration requirement in the ICR section of this rule. We estimate $13,840,515 in savings.

9. Quality Assurance and Performance Improvement Program (§ 483.75)

This rule proposes to revise the requirements in § 483.75 to provide facilities with the flexibility needed to tailor their QAPI programs to the individual needs of their specific facility. Specifically, we have proposed to remove the prescriptive requirements at § 483.75(b)(1) through (4), and § 483.75(c)(1) through (4), and all of the requirements in § 483.75(d)(2). A detailed discussion of the proposed removal of these requirements can be found in section II.A.

The proposed removal of these prescriptive requirements would focus the QAPI requirements on the expected results of the program and would no longer prescribe the structures and methods for implementing the QAPI program. This provides flexibility to the facility, as it is free to develop a creative program that meets the needs of the

facility and reflects the scope of its services and operations. We discuss the economic impact for the QAPI program in the ICR section of this rule, which represents $39,222,612 in savings.

10. Infection Control (§ 483.80)

We have proposed changing the requirement that the infection preventionist work at the facility ''part-time'' or have frequent contact with the infection prevention and control program staff at the facility, to instead require that the facility ensure that the IP has sufficient time to meet the objectives of its IPCP. Because this is more of a clarification than a change in policy, we do not anticipate any measurable impact from this revision.

11. Compliance and Ethics Program (§ 483.85(d))

We propose to reduce cost to facilities by eliminating the requirement for a dedicated compliance officer and a compliance liaison. We estimated that in carrying out this program the compliance officer (similar to an administrator) in each of the 422 organizations operating 5 or more facilities will commit 30 percent of a full time equivalent (FTE) in the compliance program operation, for a total cost of $23,436,192 (30 percent of FTE × 2080 × $89 × 422). We also estimate that in carrying out this program the compliance liaison (nursing staff) in each of 6,599 facilities will commit 10 percent of an FTE, at a total cost of $86,473,296 (10 percent of FTE × 2080 × $63 × 6,599). As such, by removing these requirements, we estimate annual savings of $109,909,488. We discussed the burden reduction for our proposed revision of the compliance and ethics program plan requirements imposed on LTC facilities in the ICR section of this rule, which estimates annual savings of $13,716,734. We estimate total annual savings for these requirements together of $123,626,222.

12. Physical Environment

Life Safety Code § 483.90(a)

At § 483.90(a) we are proposing to allow those existing LTC facilities (those that were Medicare or Medicaid certified before July 5, 2016) that have previously used the FSES to determine equivalent fire protection levels, to continue to use the 2001 FSES mandatory values when determining compliance for containment, extinguishment and people movement requirements. This would allow existing LTC facilities that previously met the FSES requirements to continue to do so without incurring great expense to change construction type—essentially undertake an effort to completely rebuild. Facilities may request a waiver of certain life-safety code requirements. The request and subsequent approval of such a waiver would constitute compliance with the Life Safety Code.

While we do not have information on the number of facilities that undertake reconstruction in a given year, we can estimate the number of facilities placed at risk of a deficiency citation by these requirements, and thus the risk of being required to rebuild the structure in order to update the building's construction type, by considering the age of the facility and the building methodologies used in given time periods. We consulted with CMS Regional Office survey staff, and based on information received from them, we estimate that 50 facilities are directly impacted by the change in the scoring of the FSES and would no longer achieve a passing score on the FSES. We estimate the average size of the affected nursing homes to be roughly 25,000 sq. ft. The cost of construction per sq. ft. is estimated at $180 in 2013 dollars (*https://www.rsmeans.com/model-pages/nursing-home.aspx*). Assuming a construction cost increase over this period of 6.5 percent using GDP deflator, the 2017 construction cost per square foot would be about $192 a square foot. The total savings from this proposal in 2017 dollars would be approximately $240 million (25,000 sq. ft. × $192 per sq. ft. × 50 facilities).

This estimate assumes that essentially all these facilities would be replaced. There are two major and offsetting trends affecting the nursing home care market in coming decades: The increasing preference and ability of elderly and disabled adults to finance and obtain long term nursing care in their own homes, and the increasing number of elderly and disabled adults as the baby boom population ages. Assuming, absent specific evidence, that these two trends roughly offset each other, the preceding estimates are a reasonable projection of likely investment costs in new (or totally reconstructed) facilities. For purposes of annual cost estimates, we assume that those costs would be spread over 5 years, and would therefore be approximately $48 million annually in those years ($240 million/5 years). There are additional uncertainties in these estimates and we therefore provide estimates that are 25 percent lower and higher in the Accounting table near the end of this RIA.

Bathroom Facilities § 483.90(f)

We are proposing to revise § 483.90(f) regarding bathroom facilities, to apply only to newly constructed facilities and newly certified facilities that have never previously been a long-term care facility. The cost of remodeling or installing a bathroom where there is none requires a substantial amount of work in some cases and may cause facilities to decide not to reopen or that the upgrade is not worth the cost. Sometimes when a facility is terminated, a new owner will come in and get newly certified. Under current requirements, the new owners would have to make the upgrades, which often times discourages new ownership (*https://www.rsmeans.com/model-pages/nursing-home.aspx*).

We estimate that there are 150 terminations per year, which we will assume come back into the program eventually under the same ownership with a new Medicare Identification Number, and that two-thirds (that is, 100) of these would have required bathroom installations. We also assume that there are 700 changes of ownership per year without the transfer of a Medicare Identification Number and provider agreement, of which about two-thirds (that is, 470) would require remodeling the bathrooms. The two-thirds estimate is an assumption based on the lack of state requirements requiring bathrooms adjacent to resident rooms. In each of the scenarios above, facility closure or the change of ownership without the transfer of a Medicare Identification Number and provider agreement necessitates reapplication for enrollment in the Medicare program. Therefore the facilities would be considered newly certified, triggering the requirements at §§ 483.90(e)(1)(i) and (f). For a wheelchair accessible bathroom with 2 fixtures (a commode and sink) the average square footage is 60 square feet. The average cost of construction per square foot was $180 in 2013 according to RSMeans construction cost data (again, *https://www.rsmeans.com/model-pages/nursing-home.aspx*). Assuming a construction cost increase over this period of 6.5 percent using the GDP deflator, the 2017 construction costs per square foot would be about $192 a square foot. The average number of residents per facility is 100/2 persons per room, giving an average of 50 bathrooms per facility. Therefore, we estimate the total first year savings for this proposal would be $576,000 based on the following: 60 sq. ft. per bathroom × 50 bathrooms × $192 per sq. ft. (inflating to 2017 dollars) = $576,000

per facility ($11,520 per room). These costs divide among terminations and change of ownership as follows:

Terminations: 100 × $576,000 = $57,600,000.

Change of Ownership: 470 × $576,000 = $270,720,000.

These calculations lead to a total first year savings estimate of $328,000,000 ($57,600,000 + $270,720,000). Second and future year savings would, however, be lower because the proportion of the existing facilities needing bathroom upgrades would have decreased each year under the October 2016 final rule. The combined number of estimated terminations and changes of ownership receiving these upgrades of 570 per year under the October 2016 final rule represents about 4 percent of the baseline stock. Presumably the likely savings from repeal of this requirement would therefore be lower by about 4 percent each year than in the year before (compounding over time as the baseline stock with such bathrooms increases). Our Accounting table's annualized estimates make this adjustment. Also, as previously described, our accounting table provides high and low estimates that are 25 percent higher or lower to emphasize the uncertainty in these estimates.

13. Informal Dispute Resolution and Independent Informal Dispute Resolution (§ 488.331 and § 488.431)

While the proposed provisions regarding the IDR and Independent IDR processes would not have significant financial burden reduction for providers, addressing issues related to the timeliness and transparency of these procedures could potentially save time and money for providers, the States, and CMS. In 2016, the completion time for the IDR process ranged from 1 day to 519 days with a median of 21 days. Providers are now required to pay CMPs into an escrow account where they are held pending a final administrative decision. For smaller facilities, having what could be a substantial amount of money held in escrow for more than a year could cause financial burden on the facility. Requiring that the process be completed in 60 days, consistent with the Independent IDR procedure, would result in a more timely return of the money being held in the case where the provider was successful in their appeal. This would also result in a financial savings to CMS as we are required to return the CMP with interest when the facility is successful. While it is impossible to place an exact dollar amount on these savings, in 2016, facilities were found non-culpable in the incidents that resulted in citations in 6 percent of IDR decisions and 12 percent of Independent IDR decisions.

The proposal specifying when the survey results should be uploaded into CASPER could not only potentially have a positive financial impact on providers but it could also have a positive impact on SAs' workload. As previously cited, in 2016, 47.31 percent of IDRs resulted in a change to the original citations. As a result of Independent IDRs, 21.8 percent of original citations were changed in some manner. If the survey results were uploaded to CASPER prior to the completion of these processes, the results could negatively impact a facility's Five-Star Quality Rating, which could not only result in a loss of business but a financial loss as well. For example, we are aware that there are payments as well as accreditation from certain organizations that are directly affected by the facility's Five-Star Quality Rating. Again, it is not possible to put a dollar amount on these savings as not all changes made based on these processes would have an impact on Five-Star Quality Ratings. For the SAs, if the information was entered prior to the completion of these processes, they would have to go back and correct any changes resulting from these processes which is valuable time that could be spent on other duties more beneficial to the protection of nursing home residents.

The proposal specifying that facilities must be provided with a written record of the final Independent IDR decision, including the Independent IDR reviewer's recommendation and, in the case where the State or CMS disagrees with that recommendation, a rationale for the disagreement, would reduce burden on providers, the States, and CMS by promoting transparency in the Independent IDR process. Providers would be given information needed to understand the final decision and no further investigation on their part would be necessary. The States and CMS would not have to respond to requests for more information as everything would be provided in the written record.

Finally, the proposal to specify that, in order to be approved as an Independent IDR reviewer, a component of an umbrella agency must have a specific understanding of Medicare and Medicaid requirements would avoid the potential for Independent IDR decisions to be challenged based on the inadequate qualifications of a reviewer. This could provide financial benefit to both providers and to CMS by avoiding unnecessary litigation. However, we have no basis for a savings calculation.

14. Civil Money Penalties: Waiver of Hearing, Reduction of Penalty Amount (§ 488.436)

Current requirements at § 488.436(a) set forth a process for submitting a written waiver of a hearing which, when properly filed, results in the reduction by CMS or the State of a facility's CMP by 35 percent, as long as the CMP has not also been reduced by 50 percent under § 488.438. We propose to restructure the waiver process by establishing a constructive waiver at § 488.436(a) that would operate by default when CMS has not received a timely request for a hearing. Since a large majority of facilities facing CMPs typically file the currently required express, written waiver, this proposed change to provide for a constructive waiver (after the 60-day timeframe in which to file an appeal following notice) would reduce the costs and paperwork burden for most facilities.

In CY 2016, 81 percent of facilities facing CMPs filed an express waiver; whereas only 4 percent of facilities facing CMPs filed an appeal and went through the hearing process. The remaining 15 percent of facilities are those who fail to waive at all or fail to waive timely when they do not appeal. We estimate that moving to a constructive waiver process would eliminate the time and paperwork necessary to complete and send in a written waiver and would thereby result in a total annual savings of $1,108,226 for LTC facilities facing CMPs as estimated in the following savings estimates ($381,800 plus $726,426 = $1,108,226).

We estimate that, at a minimum, facilities would save the routine cost of preparing and filing a letter (estimated at $200 per letter) to waive their hearing rights. In CY 2016, there were 2,360 facilities who faced CMPs. Roughly 81 percent (1,909) of these facilities filed an express, written waiver, therefore, we estimate an annual savings of $381,800 (1,909 × $200) since such letters would no longer be required to receive a 35 percent penalty reduction.

In addition, we believe that nationally some 15 percent of facilities fail to submit a waiver even though they had no intention of contesting the penalty and its basis. Under the proposed change to offer a constructive waiver by default, this 15 percent of facilities would now be eligible for the 35 percent cost reduction. We note that in CY 2016, CMS imposed a combined total of $116,387,898 in per day and per instance CMPs, with a median total amount due of $5,863. Since CMS imposed CMPs on 2,360 facilities in CY

2016, we estimate a cost savings for 354 facilities (15 percent of 2,360), the typical 15 percent who fail to submit a timely waiver request. We estimate the annual cost savings for these facilities at $726,426 ((35 percent × $5,863) × 354 facilities). For accounting purposes, this is considered a transfer between LTC facilities and the federal government.

Furthermore, we believe that the proposal to offer facilities a default constructive waiver process would also ease the administrative burden for the CMS Regional Offices. Based on our knowledge and experience, we estimate that, together, an array of individuals in each CMS Regional Office collectively spend close to 1 hour (0.80 hours) per CMP imposed to track and manage receipt of paperwork from facilities expressly requesting a waiver. Given that in CY 2016, CMS imposed a total of 2,858 CMPs on 2,360 facilities, with an average of 1.21 CMPs per facility, we estimate that CMS Regional Offices spend a total of 1,848 hours each year (0.80 hours per CMP × 1,909 facilities × 1.21 CMPs per facility) to manage the waiver paperwork. As previously noted, in CY 2016 we saw that 81 percent (1909) of the 2,360 facilities facing CMPs submitted written waivers. Because the activities involved in processing facilities' waivers requires input from individuals at varying levels within CMS, we base our estimate on the rate of $68.12 per hour on average, assuming a GS–12, step 5 salary rate of $34.06 per hour with a 100 percent benefits and overhead package. Thus, we estimate that CMS would save $125,886 per year ($68.12 per hour × 1,848 hours per year).

Total annual savings from these reforms to facilities and the federal government together would therefore be $1,233,112 ($381,800 plus $726,426 plus $125,886).

15. One-Time Implementation Costs

All of the proposals presented in the preceding analysis and detailed regulatory language changes will necessarily have to be read, understood, and implemented by affected providers. This will create one-time costs even though the underlying change reduce burden. In most cases these costs will be very low, and may be as simple as observing that a particular procedure will need only to be performed once rather than twice a year, and changing the schedule accordingly. In some cases, the facility will need to adjust in response to multiple burden reduction changes. In still other cases, time will have to be spent deciding how to change existing policy.

In total, there are about 15,639 affected entities. We assume that on average there will be 1 hour of time spent by a lawyer, 2 hours of time by facility administrator, and 2 hours of time by other staff (we assume registered nurses or equivalent in wage costs) of each affected provider to understand the regulatory change(s) and make the appropriate changes in procedures. We further estimate that 2 hours of director of nursing or facility administrator time and 2 hours of clerical time will be needed to direct and communicate changes in facility policy. Average hourly costs for these professions, with wage rates doubled to account for fringe benefits and overhead costs, are $136 for attorneys, $89 for director of nursing, $63 for registered nurses, $89 for facility administrator, and $31 for office assistant. These hourly estimates are from Table 3 and the underlying data are taken from BLS statistics for 2017, at *https://www.bls.gov/oes/current/oes_nat.htm#39-0000.*

The estimated costs for an average facility would be 1 hour at $136 and in total for attorney time, 4 hours at $89 or $356 in total for the facility administrator and director of nursing, 2 hours of time at $31 or $62 in total for clerical work, and 2 hours of time at $63 or $126 in total for other staff (RN hourly wage). For all facilities these costs add up to 15,639 times. These one-time costs add up to $680 per facility on average ($136 + $356 + $62 + $126), and in total to about $11 million (680 × 15,639 LTC facilities).

E. Effects on Small Entities, Effects on Small Rural Hospitals, Unfunded Mandates, and Federalism

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that almost all LTC facilities regulated by CMS are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The majority of long term care facilities and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). Accordingly, the savings in this proposed rule would create benefits for small entities.

The RFA requires that an Initial Regulatory Flexibility Analysis (IRFA) be prepared if a proposed rule would have a ''significant impact on a substantial number'' of such entities. HHS interprets the statute as mandating this analysis only if the impact is adverse, though there are differing interpretations. Regardless, there is no question that this proposed rule would affect a ''substantial number'' of small entities. The rule of thumb used by HHS for determining whether an impact is ''significant'' is an effect of 3 percent or more of annual revenues. These savings do not approach that threshold for most of the affected facilities. However, for those facilities that would benefit from the reforms proposed for physical environment standards, savings would far exceed the 3 percent threshold. We estimate that over one thousand facilities would benefit from these particular reforms, with total savings to these facilities exceeding $800 million in the first year. Accordingly, we have concluded that the economic effects of this proposed rule would have a significant beneficial effect on a substantial number of small entities. This RIA, together with the remainder of the preamble, meets the standards for an IRFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule affects only LTC facilities and will not have any direct impacts on small rural hospitals. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from (A) imposing enforceable duties on state, local, or tribal governments, or on the private sector, or (B) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement

programs. This proposed rule contains no such mandates.

E.O. 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This proposed rule would impose no such requirements.

F. Effects on Costs to Facilities, Providers, Medicare, Medicaid, and Patients

The immediate effects of these proposed reforms will benefit nursing facilities by reducing their costs, in some cases quite substantially, as estimated earlier in this RIA.

This proposed rule has no direct effects on the Medicare or Medicaid programs. Medicaid, however, pays for the majority of LTC costs, with more than 60 percent of residents having Medicaid as their primary payer. Medicare pays for a substantial fraction of skilled nursing care provided at these same facilities. Medicaid payment rates are set by states and it is likely that over a period of time facility savings will affect State decisions on future rates. However, there is no one-to-one correspondence. Likewise, Medicare payment rates for skilled nursing care are set based on statutory formulas and do not rapidly respond to changes in cost of care at any particular facility. It is likely, however, that in the long run most of these burden reduction savings will reduce taxpayer costs, both federal and state, under the Medicaid and Medicare programs. Private payers, both private insurance and many patients, will also benefit, but to a lesser extent since their share of nursing facility costs is relatively small.

We have not attempted to estimate effects on patients at these facilities. We do not believe that any substantial increases or reductions in the quality of patient care will result. Freeing up staff resources that are unreasonably burdensome will free up staff time available for beneficial services, but these effects are likely small and not practical to estimate. We welcome comments, however, that focus on patient care issues.

G. Alternatives Considered

Throughout this preamble we have raised issues of regulatory costs. Those reforms we have proposed are those that in our view are most likely to produce significant savings without jeopardizing patient care in any way. Indeed, reductions in unnecessary red tape free up facility resources to focus on patient care. We used the May 2017 RFI comments and previous public comments on prior rules extensively in developing these proposals.

Some specific alternative proposals we considered include modifications to the requirements for the infection preventionist to reduce costs and increase access. Ultimately, we considered current events and recent reports (as discussed in the infection control section) that indicate the prevalence of infection control concerns within nursing homes and determined it would not be appropriate to propose robust revisions to the infection control requirements at this time. Second, we considered not proposing any revisions the PRN requirements for anti-psychotic medications. However, based on concerns raised by commenters, especially the challenges highlighted by psychiatric professionals (as discussed in the pharmacy services section) we determined that a balance between resident safety and access to appropriate medications is necessary and we have solicited comment on this proposal for further insight.

Lastly, we considered not proposing any burden reducing proposals for nursing homes at this time, given that the 2016 final rule has not been fully implemented yet. However, we considered the comments received as part of the May 2017 RFI and those responses to the 2016 final rule, and determined that some modifications to the recent requirements would be appropriate at this time.

This said, there may well be significant reform options that we have not directly identified. We strongly encourage comments not only on the proposals identified in this rule, but also on other existing regulatory requirements, both to improve these proposals and to identify other beneficial reforms that we did not specifically identify. In particular, we request comments on other changes made in the 2016 final rule that could be revised or eliminated to reduce unnecessary burden.

H. Accounting Statement and Table

As required by OMB Circular A–4 (available at *www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 5, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule. As previously discussed, there are no costs that would be created under this proposed rule, and minimal transfer payments. There likely would be some benefits to residents from freeing up staff to focus on resident care rather than unnecessary paperwork and other burdens, but these are likely to be small and cannot be estimated. The primary estimate shown in this table is lower than our estimate of as much as $644 million annually in the first 5 years because we estimate that the LSC cost savings will be achieved only during the first 5 years and our annualized estimate covers 10 years. Totals are rounded to the nearest $10 million.

Table 5. Accounting Statement: Classification of Estimated Savings ($millions)

Category	Primary Estimate	Lower Bound	Upper Bound	Units		
				Year Dollars	Discount Rate	Period Covered
Benefits	None Quantifiable					
Annualized Monetized Costs (+) or Cost Reductions (-)	-$580	-$430	-$720	2017	7%	2019-2028
	-$570	-$430	-$710	2017	3%	2019-2028
Transfers	$0*					

* There is a transfer related to the costs of submitting waiver requests in the analysis of Civil

I. Reducing Regulation and Controlling Regulatory Costs

E.O. 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule will, if finalized as proposed, be considered an E.O. 13771 deregulatory action. We estimate that this rule generates $392 million in annualized cost savings in 2016 dollars, discounted at 7 percent relative to year 2016, over a perpetual time horizon. Details on the estimated cost savings from this rule can be found in the preceding analysis.

J. Conclusion

This proposed rule would substantially reduce existing regulatory requirements imposed on LTC facilities through the CoPs that Medicare and Medicaid providers must meet. The analysis in this RIA section, together with the remainder of this preamble, provides a complete RIA as well as a complete IRFA.

In accordance with the provisions of E.O. 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas X-rays.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth in Requirements for states and long term care facilities:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd).

§ 410.32 [Amended]

■ 2. Section 410.32 is amended in paragraph (d)(1)(vii) by removing the reference ''§ 483.75(k)(1)(i)'' and adding in its place the reference ''§ 483.50(a)(1)(i)''.

§ 410.78 [Amended]

■ 3. Section 410.78 is amended in paragraph (e)(2) by removing the reference ''§ 483.40(c)'' and adding in its place the reference ''§ 483.30(c)''.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

§ 482.58 [Amended]

■ 2. Section 482.58 is amended in paragraph (b)(5) by removing the reference ''483.40(d)'' and adding in its place the reference ''§ 483.40(c)''.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 3. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102, 1128I, 1819, 1871 and 1919 of the Social Security Act (42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r).

■ 4. Section 483.10 is amended by revising paragraphs (d)(3), (f)(11)(i)(F), (j)(1) and (2), and (j)(4)(i), (ii), (v), and (vii) to read as follows:

§ 483.10 Resident rights.

* * * * *

(d) * * *

(3) The facility must provide the primary care physician's name and contact information upon admission,

with any change of such information or upon the resident's request.

* * * * *

(f) * * *

(11) * * *

(i) * * *

(F) Medically-related social services as required at § 483.40(c).

* * * * *

(j) * * *

(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 to resolve grievances the resident may have, in accordance with this paragraph (j).

* * * * *

(4) * * *

(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; 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 an individual who is responsible for overseeing the grievance process.

* * * * *

(v) Ensuring that all written grievance decisions include any pertinent information including but not limited to a summary of the findings or conclusions and any corrective action taken or to be taken by the facility as a result of the grievance;

* * * * *

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

* * * * *

■ 5. Section 483.15 is amended—

■ a. In paragraph (c)(1)(ii) by removing the reference ''§ 431.220(a)(3)'' and adding in its place ''§ 431.220(a)(2)''; and

■ b. By revising paragraph (c)(3)(i).

The revision reads as follows:

§ 483.15 Admission, transfer, and discharge rights.

* * * * *

(c) * * *

(3) * * *

(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.

* * * * *

■ 6. Section 483.25 is amended by revising paragraphs (n) introductory text and (n)(1) and (2) to read as follows:

§ 483.25 Quality of care.

* * * * *

(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 use.

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

* * * * *

■ 7. Section 483.35 is amended—

■ a. In paragraph (a)(2) by removing the reference ''paragraph (c)'' and adding in its place ''paragraph (e)'';

■ b. In paragraph (e)(4) by removing the reference ''paragraph (c) of this section'' and adding in its place ''this paragraph (e)'';

■ c. In paragraph (f)(2) by removing the reference ''paragraph (d)(1)'' and adding in its place ''paragraph (f)(1)''; and,

■ d. By revising paragraph (g)(4).

The revision reads as follows:

§ 483.35 Nursing services.

* * * * *

(g) * * *

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

■ 8. Section 483.40 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Removing paragraph (c); and

■ c. Redesignating paragraph (d) as paragraph (c).

The revision reads as follows:

§ 483.40 Behavioral health services.

* * * * *

(a) In accordance with § 483.35, the facility must have sufficient staff who provide direct services to residents with competencies and skills sets that include, but are not limited to, knowledge of and appropriate training and supervision for:

* * * * *

■ 9. Section 483.45 is amended by revising paragraphs (e)(4) and (5) to read as follows:

§ 483.45 Pharmacy services.

* * * * *

(e) * * *

(4) PRN orders for psychotropic drugs are limited to 14 days. If 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 documents his or her rationale in the resident's medical record and indicates the duration for the PRN order.

(5) 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.

* * * * *

■ 10. Section 483.60 is amended by revising paragraph (a)(2) to read as follows:

§ 483.60 Food and nutrition services.

* * * * *

(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.

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

* * * * *

■ 11. Section 483.70 is amended by revising paragraph (e) introductory text and by removing paragraph (e)(3).

The revision reads as follows:

§ 483.70 Administration.

* * * * *

(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 coordination 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 biennially; and 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:

* * * * *

■ 12. Section 483.75 is amended by revising paragraphs (b), (c), and (d) to read as follows:

§ 483.75 Quality assurance and performance improvement program.

* * * * *

(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.

* * * * *

■ 13. Section 483.80 is amended by revising paragraph (b)(3) to read as follows:

§ 483.80 Infection control.

* * * * *

(b) * * *

(3) Have sufficient time at the facility to achieve the objectives set forth in the facility's IPCP.

* * * * *

■ 14. Section 483.85 is revised to read as follows:

§ 483.85 Compliance and ethics program.

(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 on 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.

(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.

(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 within the operating organization without fear of retribution.

(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:

(1) Have a more formal program that includes established written policies defining the standards and procedures to be followed by its employees.

(2) Develop a compliance and ethics program that is appropriate for the complexity of the operating organization and its facilities.

(e) *Program review.* The operating organization for each facility must periodically review and revise its compliance program to identify necessary changes within the organization and its facilities.

■ 15. Section 483.90 is amended by adding paragraph (a)(1)(iii) and revising paragraphs (d), (e)(1)(i), and (f) to read as follows:

§ 483.90 Physical environment.

* * * * *

(a) * * *

(1) * * *

(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.

* * * * *

(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 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.

(e) * * *

(1) * * *

(i) Accommodate no more than four residents. For facilities that receive approval of construction 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.

* * * * *

(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.

* * * * *

■ 16. Section 483.95 is amended by revising paragraph (f) to read as follows:

§ 483.95 Training requirements.

* * * * *

(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, 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.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 17. The authority citation for part 485 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh)).

■ 18. Section 485.645 is amended by revising paragraphs (d)(3) and (5) to read as follows:

§ 485.645 Special requirements for CAH providers of long-term care services (''swing-beds'').

* * * * *

(d) * * *

(3) Freedom from abuse, neglect and exploitation (§ 483.12(a)(1) and (2), (a)(3)(i) and (ii), (a)(4), (b)(1) and (2), and (c)(1) through (6) of this chapter).

* * * * *

(5) Social services (§§ 483.40(c) and 483.70(p) of this chapter).

* * * * *

PART 488—SURVEY, CERTIFICATION AND ENFORCEMENT PROCEDURES

■ 19. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

■ 20. Section 488.331 is amended by revising paragraph (b) to read as follows:

§ 488.331 Informal dispute resolution.

* * * * *

(b)(1) 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.

* * * * *

■ 21. Section 488.431 is amended by revising paragraphs (a)(2) and (a)(4)(i) to read as follows:

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

(a) * * *

(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.

* * * * *

(4) * * *

(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.

* * * * *

■ 22. Section 488.432 is amended by revising paragraph (c)(2) to read as follows:

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

* * * * *

(c) * * *

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

* * * * *

■ 23. Section 488.436 is amended by revising paragraph (a) to read as follows:

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

(a) *Constructive waiver of a hearing.* 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.

* * * * *

■ 24. Section 488.442 is amended by revising paragraph (a)(2) introductory text to read as follows:

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

(a) * * *

(2) *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:

* * * * *

Dated: June 24, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 26, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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