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Via Electronic Submission

September 16, 2019

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3347-P
P.O. Box 8010
Baltimore, MD 21244-1850
<http://www.regulations.gov>

Re: CMS-3347-P: Comments on Proposed Rule “Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency”

Dear Administrator Verma:

The Attorneys General of the states of New York, Illinois, Maryland, Michigan, Nevada and Oregon respectfully submit the following comments in response to Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency, 84 Fed. Reg. 138 (proposed July 18, 2019)(to be codified at 42 CFR Pts 410, 482, 483, 485 and 488), which included a request for comments on changes to the health services, protections and care of residents in Long-Term Care Facilities.¹ The recommendations that follow detail the specific concerns we have with the regulations and offer suggestions for rules to help ensure that residents of skilled nursing care facilities will have an improved quality of life. We agree with CMS that regulations of Long-Term Care (“LTC”) Facilities protect residents’ health and wellbeing. For the reasons set forth below, we believe that CMS’ proposed regulations place too great an interest on minimizing facilities’ obligations, which CMS characterizes in the proposed rule as “burdens.” We respectfully submit that declining to finalize the proposed regulations discussed below would better protect the lives of vulnerable residents of skilled nursing care facilities by (1) enhancing facility accountability to meaningful defined standards that are likely to improve resident health outcomes;

¹ Our omission of mention of a particular proposed rule in CMS-3374-P in our recommendations below is not intended to be interpreted as agreement with any such proposed rule. As a general matter, the undersigned support CMS’s maintaining the rules as they existed before the July 19, 2019 proposed rules.

(2) requiring facilities to create and maintain records that enable facilities to enhance communications between residents and administration to improve transparency, facility operations and resident care; and (3) facilitating law enforcement agencies' efforts to detect and investigate resident abuse, neglect and Medicaid and Medicare fraud in skilled nursing care facilities.

Recommendations

1. Recommendation: Maintain Current Regulation Mandating Full Patient Disclosure of Medical Providers Assisting in Their Care

We recommend maintaining current regulation mandating full patient disclosure of medical providers assisting in their care. One of the core components of the practice of medicine is a patient's informed consent for their health care. Informed consent serves several important purposes. It ensures the primacy of the patient's choice regarding their healthcare and the ability for patients to exercise agency over their own health plan. It also champions patient dignity by making sure that patients have full knowledge about their care and the risks and benefits of their health options. Additionally, as noted in the American Medical Association's ethical guidelines, "[s]uccessful communication in the patient-physician relationship fosters trust and supports shared decision making."² Having a complete listing of residents' medical staff and their contact information is essential for enabling residents to exercise informed consent and will also allow the resident, the resident's representative and the facility staff to coordinate the resident's care between his or her different providers. The proposed change would make it difficult for patients to learn about and make changes to their medical team and services, and in some cases, effectively prevent them from exercising any control over their medical team and services. The proposed change would also hinder coordination among members of the patients' medical team in making decisions to best serve patients' healthcare needs. We therefore recommend that CMS maintain the current rule, which prioritizes full informed consent through patient knowledge of their team of medical providers.

2. Recommendation: Strengthen the Grievance Process in Long-Term Care Facilities

We recommend maintaining the current regulations providing standards for facilities to address resident grievances. While we agree with the goal that CMS notes in its proposal that the grievance process should "have a positive impact on a resident's ability to voice grievances," we are concerned that the proposed changes would have the opposite effect. Specifically, we oppose the proposed regulation which distinguishes between resident "feedback" and resident "grievances" and suggests different treatment for each. While CMS' goal of putting patients about paperwork is laudable, this proposed change is problematic for several reasons that would likely adversely affect residents. First, there are insufficient definitions of what constitutes resident "feedback" and what constitutes a resident "grievance." The proposed rules state 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." The level of guidance on this vital distinction is vague and accords facilities unnecessary discretion at the expense of patient rights.

² *Code of Medical Ethics Opinion 2.1.1*, American Medical Association, (last visited September 13, 2019), <https://www.ama-assn.org/delivering-care/ethics/informed-consent>.

Many questions remain. Is it feedback or grievance when a resident complains about being brought meals of solid food that present risks of choking and aspiration that are contrary to medical orders? Is it feedback or a grievance when a resident complains that no one responded to their request for help the day before? What if the resident's request for help was to be assisted out of bed before noon? Or to be assisted with toileting in a timely manner by staff so that they were not required to soil themselves and sit for hours in that condition? Or to be transferred from a wheelchair to bed after sitting for hours waiting for assistance from staff? Is it feedback or a grievance when a resident notes that a facility door is often left unlocked? Is it feedback or a grievance when a resident expresses concern about a potential fire or safety hazard present in the facility? Without the sufficiently clear regulatory scheme of the existing regulations, the answers to these questions and the definitions of "feedback" and "grievances" are bound to vary from facility to facility resulting in non-uniform resident protections across the nation.

The multiple answers to these questions also indicate the unnecessary ambiguity and discretion that facilities would face under the proposed regulations, including the facilities that have an incentive to and predictably would likely classify serious patient complaints as "feedback." For years there have been government reports, including most recently by the Office of the Inspector General on June 12, 2019, indicating that many incidents of suspected abuse and neglect in nursing homes already go unreported.³ Likewise, NYS MFCU investigations have found some facilities already have an incentive to fail to report incidents of abuse and neglect to minimize awareness of incidents that might adversely impact their CMS Nursing Home Compare ratings and ability to attract residents to achieve maximum census. In an investigation that resulted in the conviction in 2013 of an owner of a skilled nursing care facility in upstate New York, NYS MFCU's findings included that the facility failed to report to the single state agency over 1,100 incidents of abuse and neglect in a three year period.

Second, in addition to the facilities' power to determine the definition of a "grievance" under the proposed regulation, they are also empowered to determine which complaints will undergo a full grievance investigation. This change would likely result in the unintended consequence of a lack of accountability for facilities and a corresponding lack of support for residents. Facilities would have a short-term interest in finding that few complaints rise to the level of a "grievance" due to the financial and logistical work that might be required for an investigation, and to address any findings requiring systemic change. In addition, the vagueness of the proposed standards would likely pose challenges in enforcing them. We request that CMS consider these points and prioritize resident safety and rights over temporary burdens for facilities. We recommend that CMS enact regulations that elevate the voices of vulnerable residents by providing more opportunity for redress, rather than hinder residents' capability to be heard and respected. In the long-term, the existing grievance procedure will increase facility transparency and accountability and will be enforceable. It will also improve effective communication between residents and facilities in a manner that will enable facilities to identify and address individual and systemic problems timely and effectively, and to deliver better resident health outcomes and quality of care.

Third, CMS proposes the removal of the requirement that facilities enter specified important information into a grievance report. Specifically, the new rule would not require the entry of: (a) the date the grievance was received; (b) a summary statement of the resident's grievance; (c) the steps taken to investigate the

³ HHS OIG (June 12, 2019) *Incidents of Potential Abuse and Neglect and Skilled Nursing Facilities Were Not Always Investigated and Reported*.

grievance; (d) a statement of whether the grievance was confirmed or not confirmed; and (e) the date the written decision was issued. While reducing unhelpful burdens on facilities is logical, including this information in grievance reports would add no appreciable additional administrative burden. Moreover, this data would enable the Attorneys General, OIG, state agencies, residents, and the facilities, themselves, to view data on how quickly grievances are addressed, the types of grievances at the facility and the actions taken by the facility to resolve grievances. CMS has stated in its proposal that it “expect[s] that information, such as the date the grievance was received and a summary statement of the resident’s grievance” would be added to the report “to ensure that the written decision is complete and informative.”⁴ It is unclear why CMS proposed removing these requirements when it is their expectation that those details be included. In any event, for the reasons stated above, we recommend that CMS maintain, and refrain from reducing, reporting requirements regarding a grievance in a LTC Facility.

Additionally, CMS proposes to remove all current requirements for Grievance Officials that are presently in the rules. The stated reasoning for the removal of these standards is purely to address “stakeholder concerns by allowing facilities greater flexibility in determining how their individual facility will ensure grievances are fully addressed.”⁵ However, the responsibilities CMS proposes to remove are not overly prescriptive and would be necessary in any facility’s job description for an effective grievance official. CMS proposed to remove the responsibility that the official will oversee the grievance process; will receive and track grievances; will lead any investigations; will issue grievance decisions to the resident; will maintain confidentiality associated with grievances; and will liaise with state and federal agencies as needed about any allegations. It is hard to imagine any effective oversight role for a Grievance Official without these basic requirements. To the extent that CMS wants to allow the Grievance Official to delegate part of their responsibilities to another facility employee, we recommend that CMS add text that specifically authorizes that action instead of removing core requirements necessary for an effective grievance process.

Lastly, the undersigned recommend that CMS refrain from implementing the proposed change to the retention policy for grievance records. The current law holds that facilities must maintain their grievance records for three years. The proposed regulations would reduce this figure almost by half, to a period of 18 months. Retaining grievance records for a three year period instead of an 18 month period likely poses no additional burden, and certainly poses no burden on facilities that is not outweighed by public interest. A facility that is operated in a manner that provides a high level of respect and quality of care for its residents will have relatively few grievances and will work to address them so that residents will lack reasons to lodge grievances. A facility that is operated in a manner that prioritizes owner profit over resident care and dignity will have more grievances and will need to maintain them for a sufficient period to permit appropriate accountability. In any event, any minor adverse effect on facilities having to store grievance records for 18 more months is far outweighed by the benefit of having the records accessible to residents, families, and law enforcement agencies that serve the public by enforcing laws that protect residents and the Medicaid and Medicare programs.

⁴ Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions To Promote Efficiency, and Transparency, 84 Fed. Reg. 138 (proposed July 18, 2019)(to be codified at 42 CFR Pts 410, 482, 483, 485 and 488) at 34741.

⁵ *Id.*

3. Recommendation: Maintain or Increase Facility Retention Period of Nurse Staffing Data

Although we believe it would be most beneficial to increase the retention period for nursing staffing records beyond the current requirement of 18 months, we recommend that CMS at least maintain this 18 month retention period for these important records. The resident population in LTC Facilities has increased and, in fact, it is expected that this resident population will continue to increase. As this population increases, the needs for staffing will also increase. Given these trends, we believe that the numbers of allegations of nursing home resident abuse, neglect and fraud are likely to increase. NYS MFCU has long commented about the importance of the amount and quality of staffing in nursing homes. For example, in the 2006 NYS MFCU report, “Staffing Levels in New York Nursing Homes: Important Information for Making Choices,” NYS MFCU stressed that both care and supervision provided by Registered Nurses had the strongest correlation to quality outcomes. In our investigations, NYS MFCU too often sees that facilities’ staffing problems cause abuse and neglect, and lead to unsafe and dehumanizing experiences for residents. For example, one of our investigations found that understaffing contributed to the severe neglect of a nonambulatory resident being left in a wheelchair without attendance for 41 hours.⁶ In another incident, inadequate nurse supervisor staffing led to a resident dying after none of the facility’s employees attended to the resident’s monitor sounding the alarm.⁷ In another example, NYS MFCU made findings of persistent and deficient resident care and insufficient staffing at a nursing home where a resident suffering from dementia engaged in unlawful sexual conduct with another resident, who was a female quadriplegic, in an unsupervised dining room.⁸ Records of facilities’ nursing staffing levels are crucial to our investigations of these types of incidents of abuse and neglect, as well as investigations of Medicaid provider fraud.

It is evident that gaps remain in addressing the challenge to providing quality resident care. This is reflected by the number of nursing homes with low ratings in the “staffing” category, and other categories, on Medicare.gov Nursing Home Compare website. Staffing also plays a role in Medicaid fraud. In an LTC Facility, due to the current absence of specific numeric staffing standards, staffing is a cost variable that does not directly correlate with patient census. For example, expenses such as food, medication and laundry trend with patient census, as such items are not expended if a patient does not consume them. In contrast, staffing is a cost that need not automatically increase with census, at least under current regulatory requirements. Therefore, staffing is subject to manipulation. A facility can increase its census, and the acuity of the residents it admits, and therefore its revenue (primarily from Medicaid and Medicare), while not increasing its staffing. This is because there is no explicit mandate to increase its staffing expense in response to census increases. This circumstance creates a financial incentive for the facility to maximize census while minimizing staffing costs. At the same time, ultimately, evidence reflects that proper staffing is the key element of care outcomes for residents for LTC Facilities. For each resident, the care outcome is the ultimate service or product for which skilled nursing facilities are paid by the Medicaid Program. NYS MFCU enforcement cases have shown

⁶ A.G. Underwood Announces Guilty Pleas of Former Focus Otsego Nursing Home Operators for Endangering Resident, (2018), <https://ag.ny.gov/press-release/ag-underwood-announces-guilty-pleas-former-focus-otsego-nursing-home-operators> (September 13, 2019).

⁷ A.G. Schneiderman Announces Landmark Civil Settlement with Long Island Nursing Home and Its Owners, (2016), <https://ag.ny.gov/press-release/ag-schneiderman-announces-landmark-civil-settlement-long-island-nursing-home-and-its> (June 13, 2016).

⁸ A.G. Schneiderman Announces Plea Involving Owners & Other Top Officials at Mohawk Valley Nursing Home Over Allegations of Covering-Up Resident Abuse and Neglect, (2016), <https://ag.ny.gov/press-release/ag-schneiderman-announces-plea-involving-owners-other-top-officials-mohawk-valley> (January 4, 2016).

that a facility may be aware that its approach to minimizing its staffing leads to poor patient outcomes, and that it receives sufficient additional Medicaid funds that are available to use to provide additional staffing, yet decides to retain those funds as unspent, or transfer them out of the facility.

For these reasons, facilities' maintenance of records on nursing staffing for sufficient time periods is crucial to MFCUs to be able to access them and serve their mandate of protecting the public by detecting, investigating and prosecuting resident abuse and neglect, and prosecuting Medicaid provider fraud.

Finally, according to an HHS OIG report, some states have completed surveys of their nursing homes outside of the 15 month timeframe.⁹ Therefore, we recommend that CMS at least maintain the current 18 month retention period for nursing staffing records, to account for any untimely surveys and for the other reasons stated above.

4. Recommendation: Retain Current Regulations Mandating Physician Evaluation of a Patient Prior to Extending an Order of Anti-Psychotic Drugs

The undersigned recommend that the current rule for anti-psychotic drugs remain in place, which states that physicians must reassess a patient in person prior to extending an order for anti-psychotic drugs. CMS has noted in its State Operations Manual that "PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication."¹⁰ To protect vulnerable patients from chemical restraints that violate patient rights, we recommend that CMS maintain its current regulations and guidance on prescriptions for anti-psychotic drugs.

There has been an unfortunate history of overprescribing antipsychotic drugs to vulnerable populations, including nursing home residents.¹¹ The Government Accountability Office ("GAO") drafted a report using Medicare Part D data noting that "one-third of older adults with dementia who spent more than 100 days in a nursing home in 2012 were prescribed an antipsychotic." According to a 2018 medical journal article, "[a]ntipsychotic use occurred in 11.6% of nursing home residents without qualifying or potentially qualifying diagnoses (bipolar disorder and psychotic disorder)."¹² Evidence shows that antipsychotics are associated with increased cerebrovascular morbidity and mortality among patients with dementia.¹³ Additionally, understaffing in nursing homes can lead to increased antipsychotic use for residents, which adds another layer to our concern about nursing staffing data raised in Recommendation 3.¹⁴

⁹ Brown, June Gibbs, (1999, March), Nursing Home Survey and Certification: Overall Capacity, at 14, <https://oig.hhs.gov/oei/reports/oei-02-98-00330.pdf>.

¹⁰ State Operations Manual – Appendix PP – Guidance to Surveyors for Long Term Care Facilities, CMS, Rev. 173, 11-22-17, at 506, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.

¹¹ Smith, Brendan, (2012, June), Inappropriate Prescribing, <https://www.apa.org/monitor/2012/06/prescribing> (September 13, 2019).

¹² Phillips, L.J. et al., *An Observational Study of Antipsychotic Medication Use among Long-Stay Nursing Home Residents without Qualifying Diagnoses*, J Psychiatry Mental Health Nursing 25(8), Oct 2018.

¹³ Hui et al., *A Review on Mortality Risks Associated with Antipsychotic Use in Behavioral and Psychologic Symptoms of Dementia (BPSD)*, Mental Health Clinician 6(5), Sep 2016.

¹⁴ *Id.*

Multiple government agencies and medical associations have taken notice of the overprescribing of antipsychotics to nursing home residents with dementia. Guidance from CMS and the Substance Abuse and Mental Health Services Administration (“SAHMSA”) states that “antipsychotic medications should be avoided when possible” for people with dementia with behavioral disturbances.¹⁵ The Food and Drug Administration (“FDA”) issued a warning that “the treatment of behavioral disorders in elderly patients with dementia with ... antipsychotic medications is associated with increased mortality.”¹⁶ The GAO recommended the reduction of antipsychotic use for nursing home residents with dementia.¹⁷ A publication from the American Psychological Association noted the concern of overprescribing antipsychotics to nursing home residents, noting that besides the mortality risk, “the medications ... can cause serious side effects, including muscle spasms, metabolism changes, major weight gain and an increased risk of diabetes.”¹⁸

As CMS details in its discussion of its proposal to abolish this regulation, research has found “that anti-psychotic medications were being used as chemical restraints and for the convenience of the staff in LTC facilities,” that residents “described how traumatic it was to lose their ability to stay awake, think, and communicate” as a result of the anti-psychotic drugs they were prescribed, and that “clinicians need to be mindful of, and avoid, labeling patients with other diagnoses to justify the use of medications or other treatments.”¹⁹ We care about the patients and are concerned by these documented and evidenced based recommendations by stakeholders and members of the community, and by the available data on the prevalence of overprescribing and improperly prescribing anti-psychotic drugs to individuals in nursing homes. We urge CMS to reconsider its proposal to remove the protection of requiring physicians to reassess a resident’s need for a continued regimen of anti-psychotics in person. All of the data points to the opposite conclusion—given the past abuse of these drugs and their potential danger, a close monitoring of anti-psychotic prescriptions must remain in place.

To the extent that CMS’s proposal is driven by concerns that small facilities, e.g., under 51 beds, in remote, rural areas that have submitted data that they might lack access to physicians in a timely manner, we recommend that CMS retain the current rule for all facilities, and consider craft a narrowly tailored, evidenced based exception to provide relief to such facilities, e.g., facilities that are under 51 beds in remote, rural settings that meets the documented need for an extension of a short period of time of seven days.

¹⁵SAHMSA et al., (2019, April), Guidance on Inappropriate Use of Antipsychotics: Older Adults and People with Intellectual and Developmental Disabilities in Community Settings, at 4, <https://store.samhsa.gov/product/Inappropriate%20Use%20of%20Antipsychotics%20Brief%20Guidance%3A%20Older%20Adults%20and%20People%20Living%20with%20Intellectual%20Disabilities%20in%20Community%20Settings/PEP19-INAPPUSE-BR>.

¹⁶ *Id.* at 1.

¹⁷ GAO, (2015, January), Antipsychotic Drug Use: HHS Has Initiatives to Reduce Use among Older Adults in Nursing Homes, but Should Expand Efforts to Other Settings, https://www.gao.gov/products/GAO-15-211?utm_source=blog&utm_medium=social&utm_campaign=watchblog.

¹⁸ Smith, *supra* note 7.

¹⁹ Medicare and Medicaid Programs, 84 Fed. Reg. 138 at 34743.

5. Recommendation: Retain Staffing Requirements for Food and Nutrition Staff to Increase resident Safety and Health Outcomes

To protect resident health, we recommend retaining current requirements for food and nutrition staff. Proper and individualized nutrition is a huge component of care for the elderly. Malnutrition is a persistent problem among individuals in nursing homes, occurring in 20% of the population.²⁰ That means that 1 in 5 nursing home residents will need specialized, data-driven direction for their nutritional health. The consequences of malnutrition are serious — the condition can lead to death, depression, cognitive and functional impairment and difficulty swallowing.²¹ Moreover, residents often have medical orders that prescribe nutrition requirements, such as requiring set amounts of protein, or limiting amounts of protein or sugar. For many residents, physician orders or care plans require residents' meals to be pureed, or in liquid form, or prohibit consumption of solid foods or thin liquids in order to decrease risks of life-threatening incidents of choking or aspiration. In addition to nutritional needs, the prevention of illness from foodborne pathogens is important for all individuals, but particularly vulnerable populations that live in LTC Facilities.

The proposed regulation states that individuals with two years of experience that have “completed a minimum course of study in food safety” have sufficient qualifications to be a Director of Food and Nutrition. It is unclear what a “minimum course of study” is and it appears that this clause could be interpreted as being met with an hour-long training.

To ensure that residents' nutritional needs are being met, and that their meals match the content and form required by their physicians, it is imperative to preserve the current regulations mandating specific education, experience and certification requirements for the Director of Food and Nutrition Services role

6. Recommendation: Maintain Current Regulations Regarding Annual Facility Assessments

The undersigned oppose the proposed rule that relaxes the current annual safety assessment requirement and replaces it with the need for the facility to conduct such assessments only biennially. Adding an additional year to the frequency of the requirement would allow safety hazards to go unnoticed, changes in staffing and resident populations to remain unconsidered and evolving resident health acuity and morbidity to continue unaddressed. In addition to delaying corrections that would benefit and protect residents, the proposed rule would also increase the potential liability of facilities for the detectable and avoidable tragedies that are likely to occur more frequently as a result of safety and health issues that are not timely identified and addressed.

7. Recommendation: Keep Current Regulations Regarding Quality Assurance and Performance Improvement Programs

For resident health and safety, the undersigned recommend maintaining the current Quality Assurance and Performance Improvement (“QAPI”) regulations. The proposed regulation removes most of the individual elements that must currently be present in a facility's QAPI Program. The effect of this is to render the proposed regulation too vague to be useful. CMS cites “the level of specificity and detail in the QAPI

²⁰ Bell, C.L., *Malnutrition in the Nursing Home*, Current Opinion Clinical Nutrition Metabolic Care 18(1), Jan 2015.

²¹ *Id.*

requirements... may limit a facility’s ability to design their QAPI program to fit their individual needs” as reasons that the QAPI required elements should be deleted.²² However, the required QAPI elements are all broad and leave plenty of room for facility customization of the QAPI plans. Moreover, while individualization of facilities’ QAPI programs has value, consistency in QAPI programs between facilities is also necessary and can be accomplished through keeping the current rule’s minimum common requirements. This will ensure that residents across the country benefit from a comprehensive QAPI plan.

Table 1 below contains examples of the QAPI elements the proposal would delete, along with examples of how each QAPI element could be customized for an individual facility.

Table 1: Customizability of QAPI Elements

QAPI Elements	Potential Customization
The QAPI program must “utilize the best available evidence to define and measure...quality and facility goals”;	Empowers facilities to choose specific goals relevant to their circumstances.
Facilities must include “effective systems to obtain and use of [sic] feedback and input from direct care staff, other staff, residents, and resident representatives”;	Allows facilities to choose any kind of system to collect feedback Some examples include: (i) the assignment of an employee or multiple employees to be the coordinator for feedback; (ii) a periodic survey; (iii) an anonymous drop box; and (iv) an email specifically for soliciting feedback. Similarly, the methods for using feedback can vary. Implementation could be assigned to specific staff, explored by executive leadership, or discussed in focus groups of different staff members and residents.
Facilities must include “monitoring, and evaluation of performance indicators”	Enables facilities to choose the performance indicators they want to evaluate and the frequency in which they monitor them.
Facilities must have policies addressing “[h]ow they will develop corrective actions that will be designed to effect change at the systems level to prevent quality of care, quality of life, or safety problems”	Permits each facility to develop its own corrective action plan and specify specific plans for specific goals.

As the chart above demonstrates, the elements of the QAPI program that are targeted for deletion are both crucial to the program’s success and are also broad enough such that each facility, no matter its size or location, can customize its QAPI plan and tailor the plan to its needs and resident population. For the above reasons, the OAG encourages CMS to withdraw its proposal to remove common elements of the QAPI program.

²² Medicare and Medicaid Programs, 84 Fed. Reg. 138 at 34745.

8. Recommendation: Consider Facility Size in Setting Standards for Infection Preventionists

CMS rightly explains the risks of inadequate infection control, including the fact that infection is the leading cause of morbidity and mortality in nursing homes.²³ The undersigned support maintaining the current rule regarding IPs work duration, including a minimum part time IP.

CMS' proposed regulations would change Infection Preventionists ("IPs") work duration from "at least part time" to "sufficient time ... to meet the objective's [sic] set forth in the facility's [infection prevention and control program]." Although we disagree with the premise of removing the requirement that the IP work at the facility at least part time, and with CMS' proposed rule requiring work for a "sufficient time" to meet the objectives set forth in the facility's IPCP, CMS has requested comments on how sufficiency of time should be determined. We offer that if such an approach is adopted, it would be helpful to set a standard based on meaningful factors including the number of residents in the facility, the acuity of the residents, the size of the facility, the facility's staffing levels of RNs, LPNs and CNAs, and whether the facility is experiencing or at risk of an outbreak of an infectious disease. These variables logically would affect the amount of time that an IP would need to work at a facility to meet its residents' needs, and to meet the facility's responsibilities to it employees and community to appropriately address and limit the spread of infectious diseases.

9. Recommendation: Maintain Requirements for Re-Constructed Facilities and Institute Sunset Provision for Requirements Regarding the Number of Residents per Room and Bathroom Facilities

CMS' proposed regulations restrict the current rules that there should only be two residents for each bedroom and that there must be a sink and commode in each bedroom. Under the proposal, this requirement will now only apply to (a) newly constructed facilities and (b) newly certified facilities that have never previously been a long-term care facility.²⁴ The undersigned recommend that the regulation continues to include the third category of facilities present in the current October 2016 final rules—newly re-constructed facilities.

CMS has specifically asked for comments on "whether it would be appropriate to sunset the exception [proposed] for buildings that were previously LTC Facilities" and the timeline for doing so.²⁵ While implementing the current rule seems feasible and in the best interests of the residents, if CMS is adopting a sunset exception, the undersigned would recommend a sunset provision for newly certified facilities that had previously been LTC Facilities given the anticipated costs of renovation or relocation, in addition to the disruption of services to residents for the duration of any construction project or move. We would recommend that an appropriate sunset time period would be three (3) years, given facilities have had notice of these requirements under the current regulations. At the end of that time period, if warranted for

²³ *Id.* at 34746.

²⁴ *Id.* at 34749.

²⁵ *Id.*

transactions that occur during the last half of the third year, CMS could consider permitting facilities to request extensions which may then be granted only for good cause.

10. Recommendation: Do Not Implement Delayed Reporting of Survey Results to the Certification and Survey Provider Enhanced Reports System

The undersigned recommend that facilities be required to immediately report survey results, including instances of facility noncompliance and deficiency, to the Certification and Survey Provider Enhanced Reports (“CASPER”) System so that this data is promptly added to CMS’s Nursing Home Compare. When survey reports are delivered to facilities, they accurately reflect and are based on the information available to surveyors at the time of the survey. The reports are the product of required state surveys of facilities that seek to assess compliance with statutes and regulations that facilities have notice of and are required to follow to protect resident health. In many instances, residents’ stays and care, reflected in the surveys, are funded by Medicaid and Medicare. Permitting facilities to wait to upload the data onto the CASPER system until a pending dispute resolution process has concluded would deprive residents and consumers of vital information that is accurate and relevant to their healthcare decisions, including which facility to reside in, or entrust a loved one to.

While it is not necessary, if it is feasible, an approach that may mitigate the facilities’ concern about findings pending informal dispute resolution being publicly reported would be adding a notation to a nursing home’s Nursing Home Compare profile to indicate whether there is a pending Informal Dispute Resolution or Independent Informal Dispute Resolution. If feasible, this method would ensure consumers and their families will be able to access the most up-to-date information about facilities and would accommodate facilities’ interests in having consumers know that a finding is being disputed. If it is not feasible, we respectfully submit that the interests of the residents and consumers in access to timely survey information is paramount.

11. Recommendation: Keep the Current Timeline for Phase 3

The current LTC Facility regulations provided for the Phase 3 regulations, including those regarding QAPI and compliance and ethics obligations, are to be implemented by a deadline of November 28, 2019. CMS notes that those two requirements were mandated by statute in 2012 and 2013, respectively. Therefore, facilities have had a minimum of six years notice of these requirements. Given that the deadline is a mere six weeks away, it is reasonable to expect that facilities interested in complying with regulations designed to protect residents will have either already implemented these rules or be in the process of finalizing their implementation. Under these circumstances, providing an additional year for changes that may or may not take affect would be unnecessary, and would delay the benefit to residents that the additional protections would bring if timely implemented.

CMS cites the avoidance of “unnecessary work, confusion and burden” as reasons to delay the deadline for a full year.²⁶ However, the rules are clear and the facilities have been on notice of them for six years. The facilities have been given more than enough time to implement them. Of much greater significance is the harm that would be caused by providing a deadline extension that would delay their implementation, and, as a result, delay improvements to resident safety and health. To the extent that the Phase 3 regulations are

²⁶ *Id.* at 34752.

amended, we recommend that CMS provide facilities with a one year deadline for their implementation, but not to extend the implementation deadline for the current rules.

Summary

In summary, we thank CMS for the opportunity to comment on the proposed regulations, and we request that CMS consider the safety and health concerns we have raised in this letter. We further respectfully request that CMS implement the recommendations contained herein. We believe that our recommendations strike the right balance by prioritizing residents' needs and protections without instituting unnecessary obligations for LTC Facilities. We hope that our perspective is helpful to CMS' analysis of these very important issues.

Thank you for your consideration of these comments.

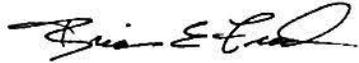
Sincerely,



Letitia James
New York Attorney General



Kwame Raoul
Illinois Attorney General



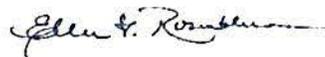
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