



State of California
Office of the Attorney General

XAVIER BECERRA
ATTORNEY GENERAL

September 16, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Comments on the Proposed Rule “Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency,” 84 Fed. Reg. 34737 (July 18, 2019), file code CMS-3347-P

Dear Secretary Azar and Administrator Verma:

Thank you for the opportunity to submit comments on the proposed rule “Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency,” 84 Fed. Reg. 34737 (July 18, 2019), issued by the U.S. Department of Health & Human Services (HHS) and the U.S. Centers for Medicare & Medicaid Services (CMS) (the Proposed Rule). For the reasons enumerated below, this proposal is an unlawful step backward for the health and safety of California’s most vulnerable residents. Not only does it violate several laws, it threatens the quality of care offered in nursing homes and other long-term care facilities. If finalized in substantially similar form, the Rule would harm an every-growing population of nursing home residents and states like California that have prioritized the safety of our residents and the public health. I urge HHS and CMS to withdraw the Proposed Rule.¹

¹ Despite CMS’s claims to the contrary, the Proposed Rule is only the most recent action your agencies have taken to weaken protections for residents of long-term care facilities. *See, e.g.,* Ensuring Safety and Quality in Nursing Homes: Five Part Strategy Deep Dive, CMS.gov



I. Background

Section 1102 of the Social Security Act (SSA) authorizes and requires the Secretaries of the Treasury, Labor, and HHS to “make and publish such rules and regulations...as may be necessary to the efficient administration of the functions with which each is charged.” 42 U.S.C. § 1302(a). Further, Section 1871 of the SSA requires the Secretary of HHS to “prescribe such regulations as may be necessary to carry out the administration” of the Medicare program. 42 U.S.C. § 1395hh(a)(1). Finally, Sections 1819 and 1919 of the SSA, which were added through the Nursing Home Reform Act, itself part of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203, 101 Stat. 1330 (1987)), create requirements for the Secretary to ensure the rights of residents of nursing homes to receive quality care and be free from abuse or exploitation.

The current regulation, issued by CMS and HHS on October 4, 2016 (the 2016 Rule), sought to update the existing regulatory scheme in light of new care delivery systems and to “improve the quality of life, care, and services in [long-term care] facilities, optimize resident safety, [and] reflect current professional standards.” 81 Fed. Reg. 68688, 68688-89. The 2016 Rule was the first major revision of long-term care facility standards since 1991, and its provisions were to be implemented in three phases on November 28, 2016, November 28, 2017, and November 28, 2019. *Id.* at 68688.

On May 4, 2017, as part of a proposed rule on the Medicare payment system, CMS requested feedback on “Possible Burden Reduction in the Long-Term Care Requirements.” 82 Fed. Reg. 21014, 21088-89. Subsequently, and without any formal rulemaking, CMS issued memoranda to decrease the amounts of Civil Money Penalties levied against non-compliant skilled nursing facilities and to delay the enforcement of the 2016 Rule.² On May 30, 2018, sixteen other state Attorneys General and I sent a letter (appended as exhibit A) expressing our concern that CMS and HHS were rolling back aspects of the 2016 Rule without undergoing a

Blog, August 28, 2019, <https://www.cms.gov/blog/ensuring-safety-and-quality-nursing-homes-five-part-strategy-deep-dive> (last visited Sept. 5, 2019).

² Revision of Civil Money Penalty (CMP) Policies and CMP Analytic Tool, S&C: 17-37-NH, July 7, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-37.pdf> (last visited Sept. 5, 2019); Revised Policies regarding the Immediate Imposition of Federal Remedies- FOR ACTION, S&C 18-01-NH, October 27, 2017, <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-18-01.pdf> (last visited Sept. 5, 2019); and Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to Nursing Home Compare, S&C 18-04-NH, November 24, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-04.pdf> (last visited Sept. 5, 2019).

formal rulemaking process. Our letter criticized the delay in the implementation of Phase 2 requirements of the 2016 Rule as well as the reduction of the Civil Money Penalties, which are key to maintaining a strong and consistent regulatory structure for long-term care facilities.

During the same time period, CMS and HHS underwent a separate rulemaking process to roll back the 2016 Rule's prohibition of pre-dispute binding arbitration agreements. "Medicare and Medicaid Programs; Revision of Requirements for Long-Term Care Facilities: Arbitration Agreements," 82 Fed. Reg. 26649 (June 8, 2017). California joined a coalition of 18 State Attorneys General who submitted comments opposing the proposed rescission on August 7, 2017 (appended as exhibit B). The final arbitration rule was published on the same day as the Proposed Rule that is the subject of this letter. "Medicare and Medicaid Programs; Revision of Requirements for Long-Term Care Facilities: Arbitration Agreements," 84 Fed. Reg. 34718 (July 18, 2019).

The Proposed Rule follows this pattern of rolling back protections, subverting statutory requirements, subjecting residents of long-term care facilities to potential harm, and putting States on the hook to ensure no gaps emerge in safety and the public health.

II. The Proposed Rule Violates the Social Security Act and Affordable Care Act

The Proposed Rule conflicts with several statutes, including Sections 1819 and 1919 of the SSA, Section 1128I of the SSA, and Section 1554 of the Affordable Care Act (ACA). The provisions in the Proposed Rule that conflict with these statutes must be withdrawn because they contravene the intent of Congress in enacting the statutes and frustrate the policy that Congress sought to implement. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-44 (1984).

A. The Proposed Rule Eliminates Resident Rights and Ignores the Secretary's Responsibilities under Sections 1819 and 1919 of the SSA

The Proposed Rule's changes include weakening the resident grievance process, allowing the use of "as-needed" psychopharmacological drugs without adequate examination, weakening protections against infection, and ignoring the Secretary's responsibility to ensure the quality of care in favor of reducing costs for facilities. These changes eliminate resident rights and disregard the responsibilities imposed upon the Secretary under Sections 1819 and 1919 of the SSA, which were added through the Nursing Home Reform Act, part of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100-203, 101 Stat. 1330 (1987)).

Grievances: Sections 1819(c)(1)(A)(vi) and 1919(c)(1)(A)(vi) of the SSA require that residents have "the right to voice grievances with respect to treatment or care that is (or fails to be) delivered, without discrimination or reprisal...and the right to prompt efforts by the facility to resolve grievances..." 42 U.S.C. § 1395i-3(c)(1)(A)(vi); § 1396r(c)(1)(A)(vi). The Proposed Rule creates a false dichotomy between grievances and "general feedback" and excludes the

latter category from the residents' statutory right to have their grievances heard and addressed. 84 Fed. Reg. at 34740. This "general feedback" exception, which has no basis in the statutes the Proposed Rule purports to implement, has the potential to swallow the right to grievance. By leaving it to the facility to determine whether a specific resident's complaint does or does not rise to the level of "grievance," the Proposed Rule creates an incentive for facilities to reduce their costs by treating even serious concerns as "general feedback" rather than employing the more thorough grievance process. *Id.* at 34741. And because items of "feedback" does not come with the guarantee of "prompt efforts...to resolve" them, 42 U.S.C. § 1395i-3(c)(1)(A)(vi); § 1396r(c)(1)(A)(vi), residents' complaints may go unaddressed.

The Proposed Rule also eliminates the position of the Grievance Officer. 84 Fed. Reg. at 34740. As the 2016 Rule explained, the purpose of the Grievance Officer is to "ensure that there is an individual who has both the responsibility and authority for ensuring, through direct action or coordination with others, that grievances are appropriately managed and resolved." 81 Fed. Reg. at 68724. The removal of the Grievance Officer will make it more difficult and complicated for residents to submit grievances. And, by eliminating the official's duties, such as tracking grievances, leading investigations, maintaining confidentiality, and issuing decisions, the Proposed Rule violates the spirit of Sections 1819 and 1919. Furthermore, the Proposed Rule lowers the requirements of what must be included in a grievance report by removing "much of the specificity," including the date received, a summary of the grievance, the investigative steps, a statement of whether the grievance was confirmed or not, and a date of decision. 84 Fed. Reg. at 34741. Under the guise of reducing "prescriptiveness" and allowing "flexibility," *id.*, the Proposed Rule will make it more difficult for a specific grievance to effect any change in a facility's policies or procedures.

Psychopharmacologic Drugs: The Proposed Rule alters the conditions under which psychopharmacologic drugs may be administered. Sections 1819(c)(1)(D) and 1919(c)(1)(D) of the SSA give residents the right that "[p]sychopharmacologic drugs may be administered only on the orders of a physician and only as part of a plan...designed to eliminate or modify the symptoms for which the drugs are prescribed..." 42 U.S.C. § 1395i-3(c)(1)(D); § 1396r(c)(1)(D). In response to evidence of overuse of such drugs to sedate residents, the 2016 Rule set a limit of 14 days for an as needed (PRN) prescription of psychotropic medications. 42 C.F.R. § 483.45(e)(4)-(5). This limit could be extended if a physician so orders and documents the rationale in the resident's medical record. *Id.* The possibility of an extension does not include antipsychotic medications, which cannot be renewed until an examination is conducted for the appropriateness of the drug. *Id.* The 2016 Rule preamble noted that the heightened standard for PRN prescriptions of antipsychotic medications was because "[a]nti-psychotic drugs continue to be a particular concern for us due to the serious side effects, including death, to elderly residents." 81 Fed. Reg. at 68771. Antipsychotic medications bear a "Black Box" warning from the U.S. Food and Drug Administration noting the increased risk of mortality in elderly patients with dementia. Easing the restrictions on the overprescription of these drugs by eliminating the distinction between antipsychotics and other classes of psychopharmacologic drugs, 84 Fed. Reg. at 34743-44, furthers a dangerous policy that is in conflict with the plain language of the SSA,

which states that these medications should be used only “to eliminate or modify the symptoms for which the drugs are prescribed.” 42 U.S.C. § 1395i-3(c)(1)(D); § 1396r(c)(1)(D).

Infection Control: Sections 1819(d)(3)(A) and 1919(d)(3)(A) of the SSA require facilities to “establish and maintain an infection control program designed to...help prevent the development and transmission of disease and infection.” 42 U.S.C. § 1395i-3(d)(3)(A); § 1396r(d)(3)(A). The Proposed Rule concedes that “[i]nfection is the leading cause of morbidity and mortality among the 1.7 million residents of United States nursing homes,” with between 1.6 and 3.8 million infections and almost 388,000 deaths each year. 84 Fed. Reg. at 34746. The Proposed Rule also mentions the financial cost of these infections, estimated at \$673 million to \$2 billion. *Id.* Nevertheless, CMS and HHS propose to remove the requirement that facilities maintain a part-time infection preventionist to oversee the facilities’ infection prevention and control programs, positing that a “sufficient time” requirement will be an appropriate standard. *Id.* at 34746-47. The weakened requirement is a dereliction of duty that will lessen oversight of facilities whose idea of “sufficient” is inadequate to meet the obligation under Sections 1819 and 1919.

Protecting Safety, Welfare, and Rights of Residents: The Proposed Rule ignores the Secretary’s responsibilities under Sections 1819(f)(1) and 1919(f)(1) of the SSA. These sections make it the “duty and responsibility of the Secretary to assure that requirements which govern the provision of care” in skilled nursing facilities and nursing facilities funded through Medicaid “are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys.” 42 U.S.C. § 1395i-3(f)(1); § 1396r(f)(1). In contrast to this mandate, the Proposed Rule seeks to lower costs and regulatory requirements for businesses in order that CMS may become a “better business partner.” 84 Fed. Reg. at 34737. The SSA never mentions a “duty and responsibility” for the Secretary to support business interests. Even though the Proposed Rule does not acknowledge harm of any kind could flow from its provisions, it is clear that residents’ interests are not the impetus behind the Proposed Rule. Such an abrogation of the Secretary’s responsibility to residents’ care in favor of cost savings violates the Social Security Act.

B. The Proposed Rule is Contrary to Section 1128I of the SSA

Section 1128I of the SSA was added through Section 6102 of the ACA and establishes the requirements for effective compliance and ethics programs and quality assurance and performance improvement (QAPI) programs for skilled nursing facilities and nursing facilities. 42 U.S.C. § 1320a-7j. The statute required the Secretary to promulgate regulations for compliance and ethics programs within two years following the enactment of the ACA and to establish a QAPI program by December 31, 2011. *Id.* 1320a-7j(b)(2)(A), (c)(1), 84 Fed. Reg. at 34752. These requirements were implemented in Phase 3 of the 2016 Rules. 42 C.F.R. §§ 483.75 (QAPI), 483.85 (compliance and ethics program); 81 Fed. Reg. at 68696.

Quality Assurance and Performance Improvement (QAPI): The intent of the QAPI program is to “establish standards relating to quality assurance and performance improvement with respect to facilities and provide technical assistance to facilities on the development of best practices.” 42 U.S.C. § 1320a-7j(c)(1). The Proposed Rule walks back the standards set out in the 2016 Rule by eliminating specific references that a QAPI program encompass a facility’s care and management practices; govern clinical care, quality of life, and resident choice; show evidence of quality that reflects processes that have been shown to be beneficial to residents; explicitly take input from staff and residents on frequent problems; establish systems to collect information from all departments; engage in adverse event monitoring; and use a systematic approach, develop corrective actions, and monitor effectiveness of performance improvement activities. 84 Fed. Reg. at 34746; *compare* 42 C.F.R. § 483.75(b), (c), (d) *with* 84 Fed. Reg. at 34766. Additionally, the Proposed Rule hints that the existing 2016 QAPI rule will be delayed past its November 28, 2019 implementation date. 42 Fed. Reg. at 34752. Taken together, these actions evidence an effort to delay and subvert the requirements of Section 1182I.

Compliance and Ethics: The compliance and ethics program under Section 1182I of the SSA is intended to be “effective in preventing and detecting criminal, civil, and administrative violations” and “in promoting quality of care.” 42 U.S.C. § 1320a-7j(b)(1). As in the case of the QAPI program, the Proposed Rule guts the detailed 2016 Rules by removing the requirement for a compliance officer, compliance liaison, and compliance and ethics program contact person; replacing the requirement of an annual review with a “periodic assessment”; scrapping annual training requirements for entities that operate five or more facilities; and eliminating the specific references to chief executive officers or board members from the list of personnel responsible for overseeing compliance. 84 Fed. Reg. at 34747-48; *compare* 42 C.F.R. § 483.85 *with* 84 Fed. Reg. at 34766-67. Again as in the case of the QAPI program, the Proposed Rule suggests a delay of the 2016 Rule’s requirements beyond the November 28, 2019 Phase 3 implementation date. 42 Fed. Reg. at 34752. Again, these provisions of the Proposed Rule show a clear effort to evade the statutory requirements of Section 1128I.

C. The Proposed Rule Conflicts with Section 1554 of the ACA

The Proposed Rule also conflicts with Section 1554 of the ACA, which explicitly prohibits the Secretary of HHS from promulgating any regulation that: “(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; [or] interferes with communications regarding a full range of treatment options between the patient and the provider...” 42 U.S.C. § 18114. The Proposed Rule would allow residents’ grievances to go unaddressed and remove requirements that residents remain informed of the names and contact information of their primary care providers. 84 Fed. Reg. at 34740-34741. These provisions create barriers for residents to consult with their providers about their care and to voice grievances if the facility designates their complaints as “general feedback” rather than a grievance. *Id.*

III. The Proposed Rule Would Violate the Administrative Procedure Act

If finalized in a substantially similar form, the Proposed Rule would violate the Administrative Procedure Act (APA) as an arbitrary and capricious agency action, 5 U.S.C. § 706(2)(A), and an action performed “without observance of procedure required by law,” § 706(2)(D).

A. The Proposed Rule is Arbitrary and Capricious Because It Removes Protections without Adequate Justification

The Proposed Rule is arbitrary and capricious because the regulatory changes discussed above are entered into without due consideration of the harms that may result. CMS and HHS recite conclusory statements that the rule changes will not harm residents, *see, e.g.*, 84 Fed. Reg. at 34763 (CMS and HHS “believe” that no reduction in the quality of care will result), but such statements are no substitute for evidence and reasoned analysis. *See McDonnell Douglas Corp. v. U.S. Dep’t of the Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004) (courts “do not defer to the agency’s conclusory or unsupported suppositions”) (citing *Motor Veh. Mfrs. Ass’n v. State Farm Ins.*, 463 U.S. 29, 44 (1983); *Occidental Petroleum Corp. v. S.E.C.*, 873 F.2d 325, 342 (D.C. Cir. 1989) (requiring more than “conclusory statement” regarding substantial competitive harm).

B. The Proposed Rule Does Not Adequately Take into Account the Harms It Will Cause

The Proposed Rule is also arbitrary and capricious because it fails to consider important regulatory costs, including any significant direct or indirect health costs to consumers and to the States. Generally, the costs of an agency’s action are “a relevant factor that the agency must consider before deciding whether to act,” and “an essential component of reasoned decision-making under the Administrative Procedure Act.” *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 732-33 (D.C. Cir. 2016); *see also Michigan v. EPA*, 135 S. Ct. 2699, 2707-08 (2015) (“Agencies have long treated costs as a centrally relevant factor when deciding whether to regulate”).

1. The Proposed Rule is Harmful to Residents of Long-Term Care Facilities

The nursing home setting presents unique risks for the development of infectious diseases, including close living quarters, age-related changes to the immune system, and the presence for many residents of co-morbidities such as diabetes, dementia, chronic obstructive lung disease, or the use of prosthetic devices.³ The most common infectious diseases in this

³ K.P. High et al., *Infectious Diseases in the Nursing Home Setting: Challenges and Opportunities for Clinical Investigation*, *Clinical Infectious Diseases* 51:8, Oct. 2010, <https://doi.org/10.1086/656411>.

setting are pneumonia, urinary tract infections, and skin and soft-tissue infections.⁴ The Proposed Rule itself notes that millions of infections occur annually in nursing homes, as a result of which 388,000 people die. 84 Fed. Reg. at 34746. Therefore, the Proposed Rule’s weakening of the standards for infection prevention by reducing the amount of time the infection preventionist must spend on site, *Id.* at 34746-47, will likely lead to more infections among this population.

Residents of nursing homes frequently suffer malnutrition, dehydration, weight loss, and vitamin and mineral deficiencies due to metabolic changes, drug interactions, depression, swallowing disorders, tooth loss, dementia, and chronic illnesses such as diabetes, and as a result may suffer an increased likelihood of hip fractures, slowed healing, and other impediments to residents’ quality of life.⁵ As a result of the specific nutritional needs of the members of this population, the Academy of Nutrition and Dietetics, the largest organization of food and nutrition specialists in the U.S., has released a position statement advocating “individualized nutrition approaches” for long-term care residents.⁶ Residents with dementia in particular benefit from person-centered nutritional care, as they can fail to recognize mealtimes and find eating difficult.⁷ The Proposed Rule’s relaxation of qualifications and credentialing standards for directors of food and nutrition services, 84 Fed. Reg. at 34744-45, will likely make it harder for residents to receive the personalized nutritional care they require for an optimal quality of life.

Over half of the Proposed Rule’s purported cost reductions—\$376 million in total—result from weakening the 2016 Rule’s standards for the physical environments in which residents live, including for fire safety and the adequacy of bathroom facilities; another \$14 million in reductions comes from reducing the frequency of facility assessments to every two years instead of annually. 84 Fed. Reg. at 34754, 34760-61. Although each of these alterations to the regulatory text come at the expense of residents’ safety, the Proposed Rule does not acknowledge any costs associated with them.

Finally, as discussed in Section II.A-B above, the Proposed Rule’s invention of a “general feedback” exception to the formal grievance process, 84 Fed. Reg. at 34740-41, will likely result in fewer concerns of residents being formally investigated and addressed, the rule’s rollback of protections against overprescription of antipsychotic medications, *Id.* at 34743-44,

⁴ *Id.*

⁵ J.E. Morley and A.J. Silver, *Nutritional Issues in Nursing Home Care*, *Annals of Internal Medicine*, Dec. 1995, <https://annals.org/aim/fullarticle/709254/nutritional-issues-nursing-home-care>.

⁶ B. Dorner et al. *Position of the Academy of Nutrition and Dietetics: Individualized Nutrition Approaches for Older Adults: Long-Term Care, Post-Acute Care, and Other Settings*, *Journal of the Am. Acad. of Nutrition and Dietetics*, April 2018, [https://jandonline.org/article/S2212-2672\(18\)30154-0/fulltext](https://jandonline.org/article/S2212-2672(18)30154-0/fulltext).

⁷ J.L. Murphy et al., *Nutrition and dementia care: developing an evidence-based model for nutritional care in nursing homes*, *BMC Geriatrics*, Feb. 2017, <https://bmcgeriatr.biomedcentral.com/articles/10.1186/s12877-017-0443-2>.

will likely lead to harm to residents' health and quality of life, and rollbacks and delays to the QAPI program and ethics and compliance program, *Id.* at 34746-48, will potentially place residents in the way of harm or civil or criminal violations.

2. The Proposed Rule Will Harm Public Health and Impose Costs and Obligations on States and State Programs

Nationwide, state-federal Medicaid is the primary payer for long-term care in nursing homes.⁸ Over 1,200 skilled nursing facilities are located in California, serving an annual population of about 400,000.⁹ Fifty-six percent of these residents have their costs covered wholly by Medi-Cal, California's Medicaid program, at an average cost of about \$220 per person per day.¹⁰ About 62,000 California residents rely on Medi-Cal for long-term care in nursing homes, 62% of the total number of long-term care residents, yielding a total expenditure of \$3.3 billion.¹¹ *See also* 84 Fed. Reg. at 34763 ("more than 60 percent of residents hav[e] Medicaid as their primary payer"). Regulatory rollbacks that result in worse conditions or poorer health for residents could drive up costs to California in terms of higher Medicaid long-term care spending.

The Proposed Rule also runs counter to California's efforts to support the health and wellbeing of all its residents. For instance, the California Department of Public Health's Center for Health Care Quality runs a Healthcare-Associated Infections Program, which has developed guidance on effective infection prevention in skilled nursing facilities.¹² The Proposed Rule's rollback of the infection preventionist requirements, 84 Fed. Reg. at 34746-47, harms California's investment in its public health and would undermine the goals of this policy.

Finally, investigations by state Medicaid Fraud Control Units (MFCUs), such as the Bureau of Medi-Cal Fraud and Elder Abuse in my office, will be hampered by the proposed alterations to the Civil Money Penalty (CMP) process. 84 Fed. Reg. at 34751. HHS and CMS propose a "constructive waiver" process. *Id.* This process would presume that a facility found in violation that does not apply for a waiver has nevertheless waived its right to contest a CMP and therefore the facility would receive the same 35 percent reduction in penalty amount as is currently available to a facility that expressly waives its right to a hearing. *Id.* The Proposed Rule touts this change as one that "would result in lower costs for most [long-term care] facilities facing CMPs." *Id.* Preemptively reducing the amounts of warranted penalties furthers the dangerous policy of CMS and HHS to reduce fines at the behest of industry, resulting in a nearly

⁸ Kaiser Family Foundation, *Medicaid's Role in Nursing Home Care*, June 20, 2017, <https://www.kff.org/infographic/medicaids-role-in-nursing-home-care/>.

⁹ California Association of Health Facilities, *Facts and Statistics*, <https://www.cahf.org/About/Consumer-Help/Facts-and-Statistics> (last visited Sept. 6, 2019).

¹⁰ *Id.*

¹¹ *Medicaid's Role*, *supra* n.9.

¹² *See*

https://www.cdph.ca.gov/Programs/CHCQ/HAI/Pages/PreventingHAI_in_LTC_Facilities.aspx.

\$13,000 drop in the average fine under the current administration as compared to 2016.¹³ MFCUs rely on CMS to provide facility oversight and beneficiary protections through a strong regulatory structure. CMPs are an essential tool for regulators to ensure facility compliance and guarantee better performance in the future. Consequently, weakening or delaying their application hampers our ability to both punish bad actors and ensure improvement, and thereby puts beneficiaries' health and lives at risk. The changes in the Proposed Rule decrease the dollar amount and frequency of penalties that—though rare and low in amount—nonetheless help safeguard Medicare and Medicaid beneficiaries. The threat of penalties is a deterrent to facilities engaging in abusive behavior. Eroding even these penalties enables unscrupulous operators to provide substandard care and receive minimal penalties, if these lapses are even brought to light. The absence of a reliable regulatory backstop could pose challenges to prosecutions of a variety of infractions, including wrongful evictions; inadequate staff training; and the absence of protections against abuse, neglect, and exploitation.

3. The Regulatory Impact Analysis in the Proposed Rule Ignores the Harms the Proposed Rule Will Cause

The Regulatory Impact Analysis (RIA) issued as part of the Proposed Rule cites annual savings of \$78 million for bypassing the grievance process, \$19 million for lowering food and nutrition standards, \$39 million for delaying and weakening QAPI programs, \$115 million for gutting compliance and ethics programs, and \$378 million for rolling back fire safety and room and bathroom standards. 84 Fed. Reg. at 34756-61. Yet despite the harms and costs detailed above, the Proposed Rule baldly states that “there are no ‘costs’ imposed by this regulation.” *Id.* at 34739. The RIA makes clear that the reason there are no costs is that CMS and HHS “have not attempted to estimate effects on patients at these facilities,” under the optimistic belief that there will be no “substantial increases or reductions in the quality of patient care.” *Id.* at 34763. That this is unlikely is shown by the evidence above. It is thus clear that CMS and HHS failed to consider important aspects of the effects of the Proposed Rule: the health costs to individual residents and the costs to the state’s public health and finances.

C. The Proposed Rule is Procedurally Invalid

The Proposed Rule is part of a deregulatory process undergone by CMS and HHS, only part of which has followed the proper rulemaking procedure. The APA requires notice in the Federal Register, an opportunity to comment, and final publication not less than 30 days before a rule’s effective date. 5 U.S.C. § 553. But before even issuing the Proposed Rule, CMS and HHS had already taken deregulatory actions without notice-and-comment rulemaking, including delaying enforcement of the Phase 2 requirements of the 2016 rule and making alterations to the

¹³ J. Rau, *Nursing Home Fines Drop As Trump Administration Heeds Industry Complaints*, Kaiser Health News, March 15, 2019, <https://khn.org/news/nursing-home-fines-drop-as-trump-administration-heeds-industry-complaints/>.

application of Civil Money Penalties.¹⁴ The lack of proper rulemaking in these earlier actions is not cured by issuing the Proposed Rule.

The Proposed Rule also foreshadows a delay of Phase 3 requirements of the 2016 Rule that are set to go into effect on November 28, 2019. 84 Fed. Reg. at 34751-52. It is implausible that CMS and HHS will be able to review the comments submitted on the Proposed Rule and issue a final rule at least 30 days prior to November 28, 2019. Therefore, any delay of the Phase 3 requirements, as suggested in the Proposed Rule, would have to be taken outside the notice-and-comment process, in violation of the Administrative Procedure Act, 5 U.S.C. § 553.

IV. Conclusion

The number of long-term care residents is increasing: the population aged 65 and older is expected to double by 2060, and one in three people turning 65 will require nursing home care during their lives.¹⁵ This societal change will require significant work and resources from those—including CMS and state authorities—who investigate abuse and undertake enforcement actions. These entities must seek to uphold the health and dignity of each individual resident as well as the overall public health. The Proposed Rule runs counter to these ideals, and in some cases subverts them. For the reasons enumerated above, I urge CMS and HHS to withdraw this harmful and unlawful proposal.

Sincerely,



XAVIER BECERRA
Attorney General

¹⁴ Revision of Civil Money Penalty (CMP) Policies and CMP Analytic Tool, S&C: 17-37-NH, July 7, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-37.pdf> (last visited Sept. 5, 2019); Revised Policies regarding the Immediate Imposition of Federal Remedies- FOR ACTION, S&C 18-01-NH, October 27, 2017, <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-18-01.pdf> (last visited Sept. 5, 2019); and Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to Nursing Home Compare, S&C 18-04-NH, November 24, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-04.pdf> (last visited Sept. 5, 2019).

¹⁵ *Medicaid's Role*, *supra* n.9.