UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL CONSUMER VOICE
FOR QUALITY LONG-TERM CARE,
1001 Connecticut Avenue, N.W.
Suite 632
Washington, DC 20036;

—and—

CALIFORNIA ADVOCATES FOR
NURSING HOME REFORM,
650 Harrison Street
2nd Floor
San Francisco, CA 94107;

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as Secretary of the U.S. Department of Health and Human Services,
200 Independence Avenue, S.W.
Washington, DC 20201;

CENTERS FOR MEDICARE AND MEDICAID SERVICES,
7500 Security Boulevard
Baltimore, MD 21244;

—and—

UNITED STATES OF AMERICA,

Defendants.

Case No. 21-162

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Plaintiffs bring this action to seek judicial review of an irregular and unlawful policy change by the Centers for Medicare and Medicaid Services ("CMS"), disseminated as sub-regulatory guidance, concerning the imposition of civil money penalties ("CMPs") for past noncompliance by long-term care facilities, including nursing facilities, with required federal standards. This policy change, announced in a July 7, 2017 memorandum from CMS to state survey agency directors, makes clear that CMS regional offices—regardless of findings and recommendations from state survey agencies—will impose a CMP for past noncompliance based *only on each instance* of noncompliance that occurred but was corrected before the state survey is conducted. With this policy change, if a facility has corrected that noncompliance just before the survey team shows up at the facility—even if the noncompliance had lasted for many months, then the facility will evade penalties *for each day* of noncompliance that may be recommended and imposed under the Nursing Home Reform Act of 1987 (NHRA) to deter and punish such gross misconduct and dereliction.

2. With the passage of the NHRA, Congress created an enforcement scheme for policing and rectifying nursing facility noncompliance with federal quality and safety standards of resident care. Congress charged CMS and the States with shared responsibility for implementing this scheme. Specifically, CMS contracts with and oversees state survey agencies that evaluate whether facilities are meeting the required federal standards, as established by Congress and interpreted and articulated by CMS.

3. Under Congress's enforcement scheme, state survey agencies regularly evaluate a nursing facility's compliance with requirements by conducting periodic, unannounced surveys. They report their findings of deficiencies to CMS regional offices and recommend appropriate enforcement action, which can include the imposition of CMPs for each day, over a previous period, that a facility was found out of compliance with federal standards. Acting on that recommendation from state survey agencies, CMS regional offices may impose per-day CMPs on a facility for past noncompliance with federal standards.

4. In announcing to state survey agency directors that its regional offices will assess CMPs *only for each instance* of past noncompliance and *not for each day* of past noncompliance, CMS's policy change contravenes Congress's express intent to give the States the discretion to recommend, and CMS the discretion to impose, a per-day CMP for past noncompliance. CMS's regulations duly implementing this effective and longstanding enforcement scheme are similarly contravened. This policy change is arbitrary and capricious, an abuse of discretion, and otherwise not accordance with law. At a minimum, it should be adjudged and declared null and void because it purports to articulate a new substantive legal standard without the required notice-and-comment rulemaking, a procedure required by law.

5. By removing per-day CMPs as an available remedy for past noncompliance, CMS's policy change has severely weakened Congress's enforcement scheme by allowing nursing facilities to knowingly let deficiencies persist for days, weeks, or even months while facing only a per-instance CMP. Because this penalty

amounts to a nothing more than the "cost of doing business" or a veritable "slap on the wrist," CMS has eliminated the incentives for facilities to self-police and take remedial measures at the earliest point possible. Those harmed by this improper and unlawful policy change include Plaintiffs: the National Consumer Voice for Quality Long-Term Care ("Consumer Voice"), an organization whose members include nursing facility residents and other consumers of long-term care services; and California Advocates for Nursing Home Reform ("CANHR"), an organization whose mission to improve the choices, care, and quality of life for consumers of long-term care services in California has been made more difficult and ineffectual by the weakened enforcement scheme.

6. The coronavirus (COVID-19) pandemic that took hold of the country beginning in early 2020 has only exacerbated the harms wrought by this policy change. For example, a recent report from the U.S. Government Accountability Office ("GAO") identified the ways in which lax enforcement and oversight, especially around critical issues like infection control, have contributed to the dangerous conditions that resulted in the pandemic taking such a perilous toll on nursing facility residents. U.S. Gov't Accountability Off., *Infection Control Deficiencies Were Widespread and Persistent in Nursing Homes Prior to COVID-19 Pandemic,* at 4 (Report No. GAO-20-576R, May 20, 2020) ("2020 GAO Report").

PARTIES

7. Plaintiff National Consumer Voice for Quality Long-Term Care, formerly known as the National Citizens' Coalition for Nursing Home Reform, is a

District of Columbia non-profit membership organization founded in 1975 with the goal of serving as the leading national voice for consumers of long-term care services. Its members include nursing facility residents and other consumers of long-term care services, who have been and will continue to be subjected to prolonged and recurring periods of noncompliance under the now weakened enforcement scheme. In addition to representing the collective interests of its long-term care consumer members in receiving quality care, the Consumer Voice empowers and educates consumers and their families so that they can advocate for themselves, and trains and supports individuals (e.g., ombudsmen) and groups who in turn empower and advocate on behalf of consumers. The effectiveness of the Consumer Voice's educational and training programs and services depends heavily on a robust federal-state enforcement scheme that appropriately sanctions long-term care facilities for their noncompliance, whether occurring in the past or ongoing. Consumer Voice's Executive Director Lori Smetanka sat on the Coronavirus Commission on Safety and Quality in Nursing Homes and testified before the Senate Committee on Finance in July 2019 on the imposition of CMPs against facilities for failing to report abuse or suspicions of a crime. Consumer Voice has formally requested that CMS vacate its guidance that makes per-instance penalties the default for past noncompliance and, instead, return to the per-day penalties provided in the NHRA.

8. Plaintiff California Advocates for Nursing Home Reform is a California non-profit advocacy organization founded in 1983 with the goal of improving the

choices, care, and quality of life for California's long-term care consumers. CANHR's programs and services are not limited to advocacy, however. Among its programs and services, the organization provides counseling to long-term care consumers regarding their complaints with facilities and their rights to redress. The effectiveness of CANHR's counseling programs and services depends heavily on a robust federal-state enforcement scheme that appropriately sanctions long-term care facilities for their noncompliance, whether occurring in the past or ongoing.

9. Defendant Alex M. Azar II, is the Secretary ("Secretary") of the United States Department of Health and Human Services ("HHS"). He is being sued in his official capacity. The Secretary maintains the headquarters in Washington, D.C.

10. Defendant Centers for Medicare and Medicaid Services is a component of HHS. Through CMS, the Secretary administers the Medicare and Medicaid programs that reimburse nursing facilities and other long-term care facilities around the country for the care and services they provide to their residents. Through CMS, the Secretary interprets, articulates, and promulgates the federal quality and safety standards of resident care that govern nursing facilities and other long-term care facilities, and oversees their enforcement in partnership with the States.

JURISDICTION AND VENUE

11. This Court has federal question jurisdiction over this case under 28 U.S.C. § 1331. Specifically, this case arises under Sections 1819 and 1919 of the Social Security Act, 42 U.S.C. §§ 1395i-3 & 1395r, respectively; the Administrative

Procedure Act, 5 U.S.C. §§ 702 & 706; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02.

12. Venue is proper in this District under 28 U.S.C. § 1391(e).

FACTUAL ALLEGATIONS

The Nursing Home Reform Act

13. In 1987 Congress passed the NHRA as part of the Omnibus Budget Reconciliation Act of 1987, Public Law No. 100–203. The NHRA introduced sweeping legislative reforms aimed at improving the quality of care and safety at nursing facilities through the establishment and enforcement of federal standards. These federal standards, codified in Sections 1819(b–d) and 1919(b–d) of the Social Security Act, broadly govern (1) the provision of care, services, and activities that promote the maintenance or enhancement of quality of life; (2) the protection and promotion of residents' rights; and (3) the effective and efficient administration and use of resources by facilities. 42 U.S.C. §§ 1395i-3(b–d) & 1396r(b–d). They apply to both nursing facilities certified under and participating in Medicare, and those dually certified under and participating in Medicare and Medicaid. *Id.*

14. For example, these federal standards require nursing facilities to "provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care [that] describes the medical, nursing, and psychosocial needs of the resident and how such needs will be met." 42 U.S.C. §§ 1395i-3(b)(2) & 1395r(b)(2). They also require facilities to protect and promote the right of each resident "to be free from

physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms." 42 U.S.C. §§ 1395i-3(c)(1)(A)(ii) & 1395r(c)(1)(A)(ii). They further require facilities to "establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection." 42 U.S.C. §§ 1395i-3(d)(3)(A) & 1395r(d)(3)(A).

15. These federal standards help to hold nursing facilities accountable for substandard care, abuse, and unsanitary and unsafe conditions that jeopardize the physical, mental, and psychosocial well-being of their residents. According to GAO, from 2013 to 2017, the most common infraction that nursing facilities are cited for related to infection control. 2020 GAO Report at 4. In fact, 82% of all surveyed nursing facilities had an infection control deficiency in at least one surveyed year. *Id.* The second most common deficiency was "ensuring the environment was free from accidents," a deficiency found in 36% of all facilities. *Id.* at 4 n. 13.

16. As seen in Sections 1819(f)(1) and 1919(f)(1) of the Social Security Act, Congress explicitly charged the Secretary with "the duty and responsibility … to assure that requirements which govern the provision of care [in nursing facilities participating in Medicare, or dually in Medicare and Medicaid], and the enforcement of such requirements, 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).

17. To ensure that nursing facilities observe and adhere to federal quality and safety standards of resident care, Congress tasked CMS and the States with the shared responsibility of administering a survey and certification process. With the exception of facilities that they themselves own and operate, the States have the primary responsibility of conducting periodic standard surveys of facilities to ascertain their compliance with federal standards, and certifying their compliance to CMS (or not) based on those survey results. 42 U.S.C. §§ 1395i-3(g)(1) & (g)(2); 42 U.S.C. § 1396r(g)(1) & (g)(2). The States may delegate the survey and certification process to designated agencies (referred to herein as state survey agencies), which enter into agreements with the Secretary to discharge these enforcement duties. 42 U.S.C. § 1395aa(a).

18. In the event that the States, through their surveys, find instances of noncompliance by nursing facilities with federal standards, Congress wisely recognized the need for financial and other consequences (including termination from program participation) severe enough to incentivize defaulting facilities to remedy the identified deficiencies promptly and expeditiously, and to take appropriate and effective measures to prevent them from recurring. Accordingly, Congress conferred on the States the discretion to recommend that the Secretary take certain enforcement action against defaulting facilities based on the nature,

scope, severity, and duration of the identified deficiencies. 42 U.S.C. §§ 1395i-3(h)(1) & 1396r(h)(1).

19. At the same time, Congress introduced a new and more flexible enforcement remedy for the Secretary and the States—a civil money penalty that could be imposed as a targeted sanction for noncompliance with any federal requirement, in lieu of the termination or nonrenewal of a defaulting facility's agreement as a participating provider, or the denial of payment for new admissions to that facility.

20. Importantly, for instances of past noncompliance, defined by statute as a situation in which a State finds that a nursing facility meets all of the federal requirements "but, as of a previous period, did not meet such requirements," Congress conferred on the States the discretion "to recommend a civil money penalty … for the days in which it finds that the facility was not in compliance with such requirements." 42 U.S.C. §§ 1395i-3(h)(1), 2d para., & 1396r(h)(1), 2d para. Plaintiffs hereinafter sometimes refer to this prescribed enforcement action under Sections 1819(h)(1) and 1919(h)(1) of the Social Security Act as a "per-day CMP for past noncompliance."

21. Congress in turn conferred on the Secretary the discretion to impose a per-day CMP for past noncompliance based on a State's findings and recommendation. 42 U.S.C. §§ 1395i-3(h)(2)(A) & 1396r(h)(2)(A). In practice, and certainly prior to the July 2017 announcement of the policy change challenged herein, "[s]pecific remedies recommended by the State are usually accepted and

imposed by CMS," as HHS's Office of Inspector General observed in an April 2005 report. U.S. Dep't of Health & Human Servs., Off. of Insp. Gen., *Nursing Home Enforcement: The Use of Civil Money Penalties,* at 1 (Report No. OEI-06-02-00720, Apr. 2005).

22. That CMS would accept and impose a per-day CMP for past noncompliance if such enforcement action were recommended by a State makes abundant sense because Congress (1) tasked the States with the first-line responsibility of surveying nursing facilities and certifying compliance with federal requirements, 42 U.S.C. §§ 1395i-3(g)(1) & (g)(2); 42 U.S.C. § 1396r(g)(1) & (g)(2), and (2) charged the Secretary with the ultimate duty and responsibility of assuring that the enforcement of such requirements is "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). It stands to reason that the Secretary could not properly discharge his duty and responsibility to assure adequate enforcement if he were to ignore a State's findings of noncompliance and recommended remedial action.

CMS's Implementing Regulations

23. In November 1994, the Secretary promulgated final regulations implementing Congress's enforcement scheme under the NHRA. Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities, 59 Fed. Reg. 56,116 (Nov. 10, 1994) (to be codified at 42 C.F.R. pt. 488). In background commentary, the Health Care Financing Administration (CMS's

predecessor agency) ("HCFA") stated that the goal of the regulations was "to promote facility compliance by ensuring that all deficient providers are appropriately sanctioned." *Id.* at 56,116.

24. HCFA therefore sought to implement Congress's mandate "to abandon [the] traditional hierarchical requirement system and develop a system capable of detecting and responding to noncompliance with any requirement." Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities, 59 Fed. Reg. at 56,117. The new enforcement system would be "built on the assumption that all requirements must be met and enforced[.]" *Id.* The selection of a particular enforcement remedy would be "based on the nature of the deficiencies and the remedy (or remedies) that either HCFA or the Medicaid State agency believes is most likely to achieve correction of the deficiencies." *Id.* HCFA believed "that remedies applied in the manner described within the proposed regulations will deter violations as well as encourage immediate response and sustained compliance." *Id.*

25. Against this backdrop, HCFA implemented the use of per-day CMPs as an enforcement remedy for both ongoing and past compliance in a regulation codified at 42 C.F.R. § 488.430:

> (a) HCFA or the State may impose a civil money penalty for the number of days a facility is not in substantial compliance with one or more participation requirements, regardless of whether or not the deficiencies constitute immediate jeopardy.
>
> (b) HCFA or the State may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy.

Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities, 59 Fed. Reg. at 56,247 (to be codified at 42 C.F.R. § 488.430). Relevant here, the per-day CMP for past noncompliance prescribed by Sections 1819(h)(1) and 1919(h)(1) of the Social Security Act became subsection (b) of this regulation.

26. HCFA finalized the regulation regarding the use of per-day CMPs, together with other regulations codified in 42 C.F.R. part 488, following notice-and-comment rulemaking—a process that took over two years. *See* Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities, 57 Fed. Reg. 39,278 (proposed Aug. 28, 1992) (to be codified at 42 C.F.R. pt. 488). In response to public comments about the imposition of per-day CMPs for past noncompliance, HCFA explained that:

> Although we may have discretion with respect to the selection of remedies to address noncompliance that is corrected by the time of a survey, it is likely that we would give serious consideration to civil money penalties in such cases. The Act, at sections 1819(h)(1) and 1919(h)(1) and (3), expressly authorizes the imposition of these sanctions even if, at the time of the survey, the facility is in substantial compliance.

Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities, 59 Fed. Reg. at 56,199. In other words, HCFA acknowledged and appreciated Congress's express authorization of per-day CMPs for past noncompliance as a directive that such an enforcement remedy is to be given serious consideration, even though the Secretary retains discretion in selecting remedies to address past noncompliance.

27. In March 1999, HCFA proposed and finalized (subject to notice-and-comment) an amendment to its regulation regarding the use of per-day CMPs to provide for the *alternative* imposition of per-instance CMPs to address cases of *ongoing* noncompliance:

> (a) HCFA or the State may impose a civil money penalty for either the number of days a facility is not in substantial compliance with one or more participation requirements *or for each instance that a facility is not in substantial compliance*, regardless of whether or not the deficiencies constitute immediate jeopardy.

Civil Money Penalties for Nursing Homes (SNF/NF), 64 Fed. Reg. 13,354, 13,360 (proposed Mar. 18, 1999) (to be codified at 42 C.F.R. § 488.430(a)) (emphasis added). Importantly here, HCFA did *not* amend subsection (b) to introduce the use of per-instance CMPs for cases of *past* noncompliance.

28. HCFA's stated rationale for expanding the enforcement remedies for cases of *ongoing* noncompliance to include the imposition of per-instance CMPs was as follows:

> Specifically, we believe the statute permits the Secretary and the States to focus on individual instances of noncompliance without having to track the duration of time that the facility remains out of compliance with those requirements (or with other program requirements). Thus, where sections 1819(h)(2)(B)(ii) and 1919(h)(2) of the Act provide that a civil money penalty may be imposed for up to $10,000 for each day of noncompliance, it is entirely consistent with the statute that HCFA or a State impose a penalty for the noncompliance it identifies without regard to additional days of noncompliance that might yet be identified. Indeed, there is nothing in the statute that compels either us or the States to await a determination of the total number of days of noncompliance

> before having the authority to react to the noncompliance that has been identified….

Civil Money Penalties for Nursing Homes (SNF/NF), 64 Fed. Reg. at 13,356. This rationale would not apply, of course, to cases of *past* noncompliance, for which the total number of days of noncompliance can be identified and determined, and a per-day CMP calculated and assessed against the facility.

29. With the exception of the substitution of "CMS" for "HCFA," subsection (b) of 42 C.F.R. § 488.430 regarding the imposition of per-day CMPs for past noncompliance has remained unchanged since its promulgation in 1994. At present, per-day CMPs range in amount, as adjusted for inflation, from $6,808 to $22,320 per day for deficiencies constituting immediate jeopardy to nursing facility residents, and from $112 to $6,695 per day for deficiencies that do not constitute immediate jeopardy but either caused actual harm or have the potential to cause more than minimal harm ("non-immediate jeopardy harm"). 42 C.F.R. § 488.438(a)(1); 45 C.F.R. § 102.3.

30. By comparison, per-instance CMPs currently range in amount, as adjusted for inflation, from $2,233 to $22,320 per instance. 42 C.F.R. § 488.438(a)(2); 45 C.F.R. § 102.3. Taking the example of a deficiency that causes non-immediate jeopardy harm, the maximum per-day CMP begins to exceed the maximum per-instance CMP whenever such a deficiency remains uncorrected for four or more days (4 x $6,695 = $26,780). Unlike a per-instance CMP, which is capped at $22,320, a per-day CMP thus punishes a nursing facility more severely

the longer it has allowed a deficiency to remain uncorrected prior to a visit by the state survey team.

CMS's Sub-Regulatory Guidance

31. In March 2007, GAO issued a report finding that although the implementation rate for CMPs increased from 32 percent for the period from July 1995 to October 1998 to 86 percent for the period from fiscal year 2003 through fiscal year 2005, "the deterrent effect of CMPs was diluted because CMS imposed CMPs at the lower end of the allowable range for the homes [GAO] reviewed." U.S. Gov't Accountability Off., *Nursing Homes: Efforts to Strengthen Federal Enforcement Have Not Deterred Some Homes from Repeatedly Harming Residents*, at 5 (Report No. GAO-07-241, Mar. 2007) ("2007 GAO Report"). The report captured the observations of one CMS official who "noted that the CMPs being imposed are not enough to 'make nursing homes take notice' or to deter them from deficient practices," and another CMS official who "stated that some homes consider CMPs a part of the 'cost of doing business' or as having no more effect than a 'slap on the wrist.'" *Id.* at 24.

32. In May 2007, the Senate Committee on Aging held a hearing to assess what the NHRA had accomplished in the twenty years since its passage and what challenges remained. Following that hearing and referencing CMS's comments in the 2007 GAO Report about CMPs being viewed by facilities as the "cost of doing business" and tantamount to a "slap on the wrist," one Senator posed the following

question for the record to Dr. Randy Farris, M.D., the regional administrator for CMS's Dallas office:

> *Sanction Effectiveness?*
>
> * * *
>
> *Question*. In addition to improvements to the actual policy, what is CMS doing to assess the enforcement capability of this particular sanction in light of these comments?

The Nursing Home Reform Act Turns Twenty: What Has Been Accomplished, and What Challenges Remain? – Hearing Before the S. Comm. on Aging, 110th Cong. 119 (2007) (App'x – question for the record from Sen. Gordon H. Smith to James Randolph Farris, M.D., Regional Adm'r, CMS).

33. In response, Dr. Farris provided the following answer:

> Answer. CMS' examination of our enforcement effectiveness in the area of Civil Money Penalties (CMPs) has been primarily along 2 tracks:
>
> 1) potential refinements to CMP maximum amounts, and
>
> 2) refinements to the decisionmaking process on imposing the CMPs.
>
> Our recent pilot and evaluation of the CMP Analytic Tool addresses the latter track. The imposition of a CMP is an optional remedy under the Nursing Home Reform Legislation promulgated in 1987. We have issued the CMP Analytic Tool. The Tool includes a scope and severity framework for CMS Regional Offices to monitor enforcement actions, communicate with States, address outliers that significantly depart from the norm, and improve national consistency.
>
> To improve national consistency for this remedy, CMS' guidance also includes a scope and severity framework for CMS to (a) monitor enforcement actions, (b) facilitate communication with

> States, and (c) address outliers that significantly depart from the norm.
>
> We expect the guidance and the CMP Analytic Tool to mitigate the extent to which civil money penalties tend to cluster at the lower end of the allowable range, particularly for nursing homes with repeated, serious quality of care deficiencies….

Id.

34. On June 22, 2007, following the Senate hearing, CMS issued a memorandum to all state survey agency directors advising them of the issuance of a "CMP Analytic Tool" that its regional offices would be using to choose, impose, and calculate CMPs whenever they determine that a CMP is an appropriate enforcement remedy. Memorandum from Director, Survey and Certification Group, to State Survey Agency Directors, Civil Money Penalty (CMP) Analytic Tool (Admin Info: 07-14, June 22, 2007) (06/22/07 Memo).

35. Although the CMP Analytic Tool apparently has been in use since the issuance of the 06/22/07 Memo, it did not become publicly available agency guidance until December 19, 2014, when CMS began posting its memoranda to all state survey agency directors updating them on any changes to or decisions regarding the CMP Analytic Tool. Memorandum from Director, Survey and Certification Group, to State Survey Agency Directors, Civil Money Penalty (CMP) Analytic Tool and Submission of CMP Tool Cases (Ref: S&C: 15-16-NH, Dec. 19, 2014) (12/19/14 Memo). CMS attached to its 12/19/14 Memo a CMP Analytic Tool User's Guide (Version 1.0).

36. In the 12/19/14 Memo, CMS explained that the goal of the CMP Analytic Tool was to promote more consistent application of enforcement remedies for nursing facilities. 12/19/14 Memo at 1. Importantly, this memorandum did not purport to dictate what enforcement remedies would or would not be appropriate for particular cases of noncompliance. *Id.* at 2 ("CMS and States may use a variety of remedies to encourage compliance."). Rather, it merely presented a consistent framework for regional offices to exercise their discretion when choosing, setting, and imposing CMPs as an enforcement remedy for compliance. *Id.* at 3 ("This tool is not intended to yield an automatic, immutable end result in the calculation of a CMP. It does not replace professional judgment or the application of other pertinent information in arriving at a final CMP amount."). The only scenario under which the CMP Analytic Tool prescribes the selection of a per-instance CMP for past noncompliance is where the dates of noncompliance cannot be determined. CMP Analytic Tool, User's Guide § 3.2 (ver. 1.0, 2014).

37. On July 7, 2017, CMS issued another memorandum to all state survey agency directors. Memorandum from Director, Survey and Certification Group, to State Survey Agency Directors, Revision of Civil Money Penalty (CMP) Policies and CMP Analytic Tool (Ref: S&C: 17-37-NH, July 7, 2017) (07/07/17 Memo). Unlike the prior memoranda, this one purports to effectuate a policy change, as the subject line suggests. Specifically, this memorandum purports to:

> **Past Noncompliance:** ROs *will impose* a per-instance CMP for past noncompliance – something occurred before the current survey, but has been fully addressed and the facility is back in compliance with that area.

> **Per Instance CMP is t*he Default* for Noncompliance that Existed before the Survey:** CMS ROs will generally impose a Per Instance CMP retroactively for non-compliance that still exists at the time of the survey, but began earlier….

Id. at 2 (emphases added).

38. CMS apparently instituted this policy change in response to lobbying from the nursing facility industry, which decried what it described as "a dramatic increase in CMPs being retroactively issued and used as punishment." *See* Letter from Mark Parkinson, President & CEO, American Health Care Ass'n, to Thomas E. Price, M.D., Sec'y, U.S. Dep't of Health & Human Servs., at 4 (Mar. 9, 2017) (copy attached as Exhibit A). The industry "asked that CMS issue a new Survey and Certification policy memorandum that specifies CMPs can no longer be retroactive[.]" *Id.*

39. The effect of this announced policy change is to nullify the discretion that the States have, under Sections 1819(h)(1) and 1919(h)(1) of the Social Security Act and 42 C.F.R. § 488.430(b), to recommend the imposition of per-day CMPs for cases of past noncompliance. After all, if CMS will only consider per-instance CMPs for past noncompliance, then any contrary recommendation from the States is futile and of no moment.

40. The effect of this announced policy change is to cabin the discretion that CMS's regional offices have, under Sections 1819(h)(2)(A) and 1919(h)(2)(A) of the Social Security Act and 42 C.F.R. § 488.430(b), to consider the imposition of per-day CMPs for cases of past noncompliance.

41. The announced policy change thus contravenes Congress's express authorization, under Sections 1819(h) and 1919(h) of the Social Security Act, of per-day CMPs as enforcement remedies for past noncompliance, which the Secretary previously acknowledged in November 1994 to be a directive that per-day CMPs be given "serious consideration" when exercising discretion in selecting one or more available remedies to address past noncompliance.

42. The announced policy change thus irreconcilably conflicts with CMS's own regulation, 42 C.F.R. § 488.430(b), which authorizes both CMS and the States to impose per-day CMPs as enforcement remedies for past noncompliance, and which the Secretary chose not to amend to provide per-instance CMPs as an alternative remedy in March 1999.

43. The announced policy change, disseminated as sub-regulatory guidance, cannot override substantive legal standards enunciated in either a statute enacted by Congress or implementing regulations promulgated by the Secretary. Furthermore, the announced policy change, in stark contrast to CMS's regulation, 42 C.F.R. § 488.430(b), is not the product of notice-and-comment rulemaking. Instead, CMS announced it without any forewarning of or any rationale behind the policy shift.

44. Although CMS did not elicit comments on this change, several Attorneys General and consumer advocates including AARP have notified the agency in letters that this change would eliminate critical incentives for nursing facilities to address dangerous conditions at the earlier possible point. *See* Letter

from Xavier Becerra, Cal. Att'y Gen., et al. to Alex M. Azar II, Sec'y, U.S. Dep't of Health & Human Servs. & Seema Verma, Adm'r, Ctrs. for Medicare & Medicaid Servs. (May 30, 2018) (copy attached hereto as Exhibit B); Letter from David Certner, Legislative Counsel & Legislative Pol'y Dir., AARP, to Dr. Kate Goodrich, Dir. & Chief Med. Officer, Ctrs. for Medicare & Medicaid Servs. (Jan. 2, 2019) (copy attached hereto as Exhibit C). These concerns have gone unheeded.

Impact of the Announced Policy Change

45. The Plaintiffs have been adversely impacted by the announced policy change in CMS's July 7, 2017 memorandum.

46. As noted above, per-instance CMPs currently range in amount, as adjusted for inflation, from a minimum of $2,233 to a maximum of $22,320 for each instance of noncompliance. 42 C.F.R. § 488.438(a)(2); 45 C.F.R. § 102.3. Taking again the example of a non-immediate jeopardy deficiency, the maximum per-instance CMP that a nursing facility faces for this type of deficiency is $22,320, regardless of whether the facility has allowed the deficiency to remain uncorrected for one day, one week, or one month. By contrast, the maximum per-day CMP for this type of deficiency begins to exceed, and quickly dwarfs, the maximum per-instance CMP whenever the facility has allowed the deficiency to remain uncorrected for four or more days (4 x $6,695 = $26,780).

47. The imposition of only per-instance CMPs for past noncompliance will thus encourage nursing facilities to knowingly allow deficiencies to linger, unaddressed for multiple days, weeks, or even months until the next state survey,

because the penalty will be the same regardless of whether the deficiency persisted for one day, thirty days, ninety days, or nine months. As long as the facility remedies the deficiency before the next survey is conducted (and standard surveys are spaced 12 to 15 months apart), it can be fined only up to the per-instance maximum of $22,320.

48. An enforcement scheme that relies exclusively on the imposition of per-instance CMPs to address past noncompliance is a severely weakened and toothless one. The financial penalties will never be more than the "cost of doing business" or a veritable "slap on the wrist," as noted in the 2007 GAO Report. They will never be significant enough to incentivize prompt and expeditious actions to eliminate the dangerous deficiencies and prevent them from recurring. As a consequence, residents' lives are placed at risk, as the country has seen with great clarity during the COVID-19 pandemic.

49. Plaintiff Consumer Voice represents nursing facility residents and other long-term care consumers who face palpable and continuing risk of being subjected to physical, mental, or psychosocial harm in their respective facilities if the incentives for immediate corrective action are not present. For a resident, each day of noncompliance is one extra day in which some injury (or death) from substandard or unsafe care, or some violation of his or her fundamental rights, could befall him or her. Consumer Voice itself is also negatively impacted because the effectiveness of its educational programs teaching long-term care consumers to advocate for themselves, and its training programs supporting ombudsmen who

advocate on behalf of consumers and their families, relies on a robust enforcement scheme that is responsive to complaints lodged by residents, their family members, and their ombudsmen. If nursing facilities do not fear the assessment of massive financial penalties for their noncompliance, they will much less inclined to address complaints from residents and their ombudsmen promptly and expeditiously.

50. Like the Consumer Voice, Plaintiff CANHR similarly counsels long-term care consumers in California to advocate for themselves. Its interests are also negatively impacted because the effectiveness of CANHR's programs and services for long-term care consumers in California relies on a robust enforcement scheme that is responsive to complaints lodged by residents, their family members, and their ombudsmen.

51. Both the Consumer Voice and CANHR have had to expend resources to compensate for a severely weakened enforcement scheme caused by CMS's announced policy change regarding the imposition of per-instance CMPs for past noncompliance.

CAUSE OF ACTION

Violations of the Social Security Act and the Administrative Procedure Act

52. Plaintiffs reallege and incorporate by reference all of the allegations in the preceding paragraphs.

53. CMS's announced policy change in its July 7, 2017 memorandum violates the plain language of Sections 1819(h)(1), 1819(h)(2)(A), 1919(h)(1), and 1919(h)(2)(A) of the Social Security Act, which expressly confer discretion on

the States to recommend per-day CMPs for past noncompliance and discretion on the Secretary to impose per-day CMPS for past noncompliance. 42 U.S.C. §§ 1395i-3(h)(1) & (h)(2)(A); 1396r(h)(1) & (2)(A). The policy change, which nullifies or cabins the discretion conferred by Congress, exceeds CMS's statutory authority, *see* 5 U.S.C. § 706(2)(C).

54. CMS's announced policy change in its July 7, 2017 memorandum constitutes an abrupt and irregular departure from its own regulation, 42 C.F.R. § 488.430(b), which expressly authorizes CMS and the States to impose per-day CMPs for past noncompliance. Furthermore, CMS could have amended, but chose not to amend, this regulation to add per-instance CMPs as an alternative enforcement remedy. Without a principled basis for this departure from a regulation that governs the very issue, the policy change is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, *id.* § 706(2)(A).

55. CMS's announced policy change in its July 7, 2017 memorandum was effectuated without the benefit of notice-and-comment rulemaking, in stark contrast to its regulation governing the imposition of per-day and per-instance CMPs, 42 C.F.R. § 488.430. In the absence of the required notice-and-comment rulemaking under the Administrative Procedure Act, 5 U.S.C. § 553, the policy change lacks observance of procedure required by law, *id.* § 706(2)(D).

56. Even if the Administrative Procedure Act does not require notice-and-comment rulemaking for CMS's announced policy change in its July 7, 2017 memorandum, the policy change nevertheless constitutes sub-regulatory guidance

that is invalid under *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019), because it purports to articulate a substantive legal standard under the Social Security Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court:

A. Declare that CMS's announced policy change in its July 7, 2017 memorandum violates the plain language of the Social Security Act, 42 U.S.C. §§ 1395i-3(h) & 1396r(h); exceeds CMS's statutory authority, 5 U.S.C. § 706(2)(C); is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, 5 U.S.C. § 706(2)(A); 42 C.F.R. § 488.330(b); fails to observe procedure required by law, 5 U.S.C. §§ 553, 706(2)(D); and constitutes improper and invalid sub-regulatory guidance, *Azar v. Allina Health Servs.*, 139 S. Ct. 1804 (2019);

B. Set aside CMS's announced policy change in its July 7, 2017 memorandum as exceeding CMS's statutory authority; as arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law; as lacking observance of procedure required by law; and as constituting invalid sub-regulatory guidance;

C. Declare that CMS may not lawfully require its regional offices to impose only per-instance CMPs for past noncompliance, in derogation of findings and recommendations to the contrary from the States; and

D. Provide such further relief as the Court may deem just and proper.

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Respectfully submitted,

/s/ Kelly Bagby

Kelly Bagby (D.C. Bar No. 462390)
kbagby@aarp.org
AARP FOUNDATION
601 E Street, NW
Washington, DC 20049
Tel: (202) 434-2103
Fax: (202) 434-6424

/s/ Henry C. Su

Henry C. Su (D.C. Bar No. 441270)
hsu@constantinecannon.com
CONSTANTINE CANNON LLP
1001 Pennsylvania Street, NW
Suite 1300N
Washington, DC 20004-5979
Tel: (202) 204-3504
Fax: (202) 2044-3501