

United States Senate

WASHINGTON, DC 20510

August 27, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Verma:

Nursing homes continue to be at the epicenter of the spread of the novel coronavirus disease 2019 (COVID-19) in the United States. To date, over 70,000 residents and workers in nursing homes and other long-term care settings have lost their lives to COVID-19, and more than 378,000 have been infected.¹ Recent reports from state inspection officials have revealed that in more than one such facility, residents were treated with hydroxychloroquine without their informed consent or without approval from state officials. Such actions may be in violation of Centers for Medicare and Medicaid Services (CMS) rules that provide resident the right to “to be informed of, and participate in, his or her treatment.”² The use of hydroxychloroquine is all the more concerning due to warnings from medical experts about the increased risks seniors face from the drug due to its effect on heart rhythms, renal systems and interactions with other medications.³

As the agency with primary responsibility for oversight of nursing homes participating in Medicare and Medicaid, we write to request information on what CMS is doing to monitor the use of hydroxychloroquine by nursing homes and to ensure that resident rights are adequately protected. Further, we urge CMS to investigate this matter using data already maintained and collected by CMS, including Medicare claims data and available inspection reports.

Early in the pandemic, and without significant study or consensus among the scientific community, the Trump Administration inappropriately looked to hydroxychloroquine as a potential treatment for

¹ The COVID Tracking Project, “The Long-Term Care COVID Tracker,” <https://covidtracking.com/data/longtermcare> (last visited August 26, 2020).

² 42 CFR §483.10(c).

³ e.g. Alicia Lasek, “Malaria drugs approved for COVID-19 use: Geriatrician warns of side effects in elderly,” McKnights Long-Term Care News, March 30, 2020, <https://www.mcknights.com/news/clinical-news/malaria-drugs-approved-for-covid-19-use-geriatrician-warns-of-side-effects-in-elderly/>; Vivian Nava-Schellinger, et al., “Hydroxychloroquine (Plaquenil) and COVID-19: An Interview with Experts,” National Council on Aging Blog, April 22, 2020, <https://www.ncoa.org/blog/hydroxychloroquine-plaquenil-and-covid-19-an-interview-with-experts/>; Kelly Servick, “Antimalarials widely used against COVID-19 heighten risk of cardiac arrest. How can doctors minimize the danger?,” Science Magazine, April 21, 2020, <https://www.sciencemag.org/news/2020/04/antimalarials-widely-used-against-covid-19-heighten-risk-cardiac-arrest-how-can-doctors>.

COVID-19.⁴ President Trump even went so far as to tout the drug's benefits, noting that use of the drug could be "one of the biggest game changers in the history of medicine."⁵ For a limited time, this drug, which is commonly used to treat several other conditions, was given an Emergency Use Authorization (EUA) for the experimental treatment of COVID-19 in supervised, hospital settings.⁶ This authorization was later revoked by the Food and Drug Administration (FDA).⁷ Although the FDA and the scientific community have now concluded that hydroxychloroquine is not an effective treatment for COVID-19, and that it can even have serious side effects for some individuals, the Trump Administration continues to issue misleading statements regarding the efficacy and safety of this drug as a treatment for COVID-19.⁸ This mixed messaging from the Trump Administration, coupled with an absence of clear guidance, has led to the drug's continued use, even after the FDA issued warnings about its safety.⁹

Recent state inspection reports of nursing homes in Pennsylvania and Texas reveal that residents were treated with hydroxychloroquine without state authorization and without the informed consent of the residents or their family members or guardians. Nationwide, nursing homes are required to ensure that residents or their guardians "are fully informed and understand their health status, care and treatments,"¹⁰ and in some states, the use of experimental or off-label treatments, like hydroxychloroquine to treat COVID-19, may only take place with the consent and consultation of the state's health department.¹¹

⁴ Katie Thomas and Denise Grady, "Trump's Embrace of Unproven Drugs to Treat Coronavirus Defies Science," New York Times, March 20, 2020, <https://www.nytimes.com/2020/03/20/health/coronavirus-chloroquine-trump.html>; Marisa Taylor and Aram Roston, "Pressed by Trump, U.S. pushed unproven coronavirus treatment guidance," Reuters, April 4, 2020, <https://www.reuters.com/article/us-health-coronavirus-usa-guidance-exclu/exclusive-pressed-by-trump-u-s-pushed-unproven-coronavirus-treatment-guidance-idUSKBN21M0R2>; Jared Hopkins, "States Try Reducing Malaria-Drug Hoarding Amid Unproven Coronavirus Benefit," Wall Street Journal, April 6, 2020, <https://www.wsj.com/articles/states-try-reducing-malaria-drug-hoarding-amid-unproven-coronavirus-benefit-11586095200>

⁵ Libby Cathey, "Timeline: Tracking Trump alongside scientific developments on hydroxychloroquine," ABC News, August 8, 2020, <https://abcnews.go.com/Health/timeline-tracking-trump-alongside-scientific-developments-hydroxychloroquine/story?id=72170553>.

⁶ U.S. Food & Drug Administration, Coronavirus (COVID-19) Update: Daily Roundup March 30, 2020, March 30, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-march-30-2020>.

⁷ U.S. Food & Drug Administration, Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine, June 15, 2020, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and>.

⁸ Quint Forgey and Caitlin Oprysko, "'I happen to think it works': Trump doubles down on hydroxychloroquine," Politico, July 28, 2020, <https://www.politico.com/news/2020/07/28/fauci-trump-ineffective-coronavirus-treatment-383809>; Anne Gearan, et al., "Trump says he is taking hydroxychloroquine to protect against coronavirus, dismissing safety concerns," Washington Post, May 18, 2020, https://www.washingtonpost.com/politics/trump-says-he-is-taking-hydroxychloroquine-to-protect-against-coronavirus-dismissing-safety-concerns/2020/05/18/7b8c928a-9946-11ea-ac72-3841fcc9b35f_story.html.

⁹ David Knowles, "Hydroxychloroquine still being used to treat coronavirus," Yahoo News, May 1, 2020, <https://news.yahoo.com/hydroxychloroquine-still-being-used-to-treat-coronavirus-213655822.html>; Faith Abubey, "VA still using controversial drug on Georgia veterans with COVID-19 despite FDA warning," 11 Alive, April 29, 2020, <https://www.11alive.com/article/news/investigations/va-still-using-hydroxychloroquine-despite-fda-warning/85-aec06401-4979-4273-888c-ce0a85ff21c8>.

¹⁰ 42 CFR §483.10(c).

¹¹ Centers for Medicare and Medicaid Services, State Operations Manual Appendix PP – Guidance to Surveyors for Long Term Care Facilities, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf; 28 Pa. Code § 201.29(o).

In Pennsylvania, where consultation with the state health department is required, one nursing home treated 205 of their 435 residents using hydroxychloroquine without proper approval from state officials.¹² According to a state inspection report issued on June 18, not only was this treatment undertaken without consultation with the state, it was still taking place five days after the FDA issued warnings against its use in non-hospital settings.¹³ Additionally, according to the report, the nursing home failed to “report medication errors and adverse events occurring during Hydroxychloroquine [*sic*] sulfate treatment, as required by the EUA.”¹⁴ In Texas, state inspection reports reveal that that a nursing home was cited for treating cognitively impaired patients for COVID-19 without getting consent from their family or guardians first.¹⁵ Because inspection records are redacted to preserve patient privacy, it is not clear what drugs they were given. However, media reports indicate that this same facility was using hydroxychloroquine to treat patients with COVID-19.¹⁶

The above cases, in Pennsylvania and Texas, represent just two examples where nursing home residents were improperly treated with this controversial drug. While these were captured by the limited infection control and complaint inspections that have been taking place in nursing homes since the start of the pandemic, with regular inspections suspended and visitation by families and long-term ombudsman limited, it is possible that other instances like these have gone unchecked. For months, media reports have indicated that nursing homes across the United States used hydroxychloroquine to treat residents.¹⁷ In one case, a nursing home for veterans in Pennsylvania

¹² Pennsylvania Department of Health, Brighton Rehabilitation and Wellness Center Patient Care Inspection Results, June 18, 2020, <https://sais.health.pa.gov/commonpoc/Content/PublicWeb/ltc-survey.asp?Facid=020802&PAGE=1&NAME=BRIGHTON+REHABILITATION+AND+WELLNESS+CENTER&SurveyType=H&COUNTY=BEAVER>.

¹³ Pennsylvania Department of Health, Brighton Rehabilitation and Wellness Center Patient Care Inspection Results, June 18, 2020, <https://sais.health.pa.gov/commonpoc/Content/PublicWeb/ltc-survey.asp?Facid=020802&PAGE=1&NAME=BRIGHTON+REHABILITATION+AND+WELLNESS+CENTER&SurveyType=H&COUNTY=BEAVER>; U.S. Food & Drug Administration, “FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems,” April 24, 2020, <https://www.fda.gov/drugs/fda-drug-safety-podcasts/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or>.

¹⁴ Pennsylvania Department of Health, Brighton Rehabilitation and Wellness Center Patient Care Inspection Results, June 18, 2020, <https://sais.health.pa.gov/commonpoc/Content/PublicWeb/ltc-survey.asp?Facid=020802&PAGE=1&NAME=BRIGHTON+REHABILITATION+AND+WELLNESS+CENTER&SurveyType=H&COUNTY=BEAVER>.

¹⁵ The Resort at Texas City, Health Inspection Survey on May 13, 2020 Report, <https://www.cms.gov/files/zip/nursing-home-infection-control-surveys.zip>.

¹⁶ Nick Powell, “Even after deaths and positive tests, Texas City doctor declares victory with Trump-touted drug,” Houston Chronicle, May 14, 2020, <https://www.houstonchronicle.com/news/houston-texas/houston/article/texas-city-nursing-home-doc-unproven-trump-drug-15270476.php>

¹⁷ Nick Powell, “Even after deaths and positive tests, Texas City doctor declares victory with Trump-touted drug,” Houston Chronicle, May 14, 2020, <https://www.houstonchronicle.com/news/houston-texas/houston/article/texas-city-nursing-home-doc-unproven-trump-drug-15270476.php>; Vinny Vella, “Pennsylvania nursing homes are treating coronavirus patients with the unproven malaria drug Trump touted — sometimes without consent,” The Philadelphia Inquirer, May 11, 2020, <https://www.inquirer.com/news/coronavirus-nursing-homes-pennsylvania-hydroxychloroquine-pennsylvania-broomall-southeastern-veterans-center-20200511.html>; “NCDHHS receives 1.5 million hydroxychloroquine tablets for long term care facilities, hospitals,” WSOCTV, April 24, 2020, <https://www.wsocvtv.com/news/local/fda-warns-about-antimalarial-drug-being-tested-covid-19-patients/OJZ7L4L3SBCAVIKNNXAPKVRED4/>; Andrew Selsky, “Oregon OKs malaria drug for COVID-19 patients in care facilities, prisons,” KVAL, April 2, 2020, <https://kval.com/news/local/oregon-oks-malaria-drug-for-covid-19-patients-in-care-facilities-prisons>; Nolan Clay, “Coronavirus in Oklahoma: More Norman nursing home residents test positive,” The Oklahoman, April 1, 2020, <https://oklahoman.com/article/5659094/coronavirus-in-oklahoma-more-norman-nursing-home-residents-test-positive>.

reportedly referred to hydroxychloroquine as an ingredient in their “Covid Cocktail” and administered it to residents as a preventive measure.¹⁸ According to family and residents, consent was not given for the use of this treatment.¹⁹

Despite these reports and now official state inspection reports indicating the inappropriate use of this drug, CMS has failed to issue guidance to nursing homes on the use of hydroxychloroquine. Furthermore, despite the availability of Medicare data and information provided by some state surveyors through infection control inspections, is not clear whether CMS is adequately monitoring the treatment of COVID-19 patients in nursing homes to determine how widespread the use of hydroxychloroquine is and whether its use has resulted in adverse outcomes for residents.

To help us understand what CMS has done to monitor the use of hydroxychloroquine in nursing homes, and communicate with nursing home operators, residents and states regarding the inappropriate use of this treatment, we request the following information:

- 1) Please provide any guidance or other documentation issued by CMS on the use of hydroxychloroquine to nursing homes and providers associated with these facilities.
- 2) Medical experts have raised specific concerns about using hydroxychloroquine to treat elderly patients because of various comorbidities and interactions with commonly used prescription medication. Please provide any guidance or other documentation issued by CMS on the use of hydroxychloroquine to nursing homes to state survey and licensing agencies, including any guidance on monitoring such use.
- 3) Please provide the number of payments made by Medicare for the use of hydroxychloroquine to treat COVID-19 patients or prevent COVID-19 infections in nursing homes, since March 1, 2020, including whether such use occurred before, during or after the Emergency Use Authorization was in place. Please indicate the number of doses of hydroxychloroquine covered by these payments.
- 4) Please provide the number of Medicare claims that indicate that the hospitalization was related in whole or in part to hydroxychloroquine being administered.
- 5) Has CMS taken any steps, or directed state survey agencies to take any steps, to monitor the use of hydroxychloroquine to treat residents for COVID-19 in nursing homes? If so please describe the steps that have been taken and provide any data that has been collected.
- 6) Has CMS received any complaints related to the use of hydroxychloroquine in nursing homes to treat or prevent COVID-19? If so, please provide de-identified versions of those reports and complaints.
- 7) Has CMS or its regional offices received any outreach from state agencies on the use of hydroxychloroquine in nursing homes? If so please describe that outreach and provide any correspondence associated with it.

¹⁸ Debbie Cenziper and Shawn Mulcahy, “The ‘Covid Cocktail’: Inside a Pa. nursing home that gave some veterans hydroxychloroquine even without covid-19 testing,” Washington Post, July 7, 2020, <https://www.washingtonpost.com/business/2020/07/07/covid-cocktail-inside-pa-nursing-home-that-gave-some-veterans-hydroxychloroquine-even-without-covid-19-testing/>.

¹⁹ Debbie Cenziper and Shawn Mulcahy, “The ‘Covid Cocktail’: Inside a Pa. nursing home that gave some veterans hydroxychloroquine even without covid-19 testing,” Washington Post, July 7, 2020, <https://www.washingtonpost.com/business/2020/07/07/covid-cocktail-inside-pa-nursing-home-that-gave-some-veterans-hydroxychloroquine-even-without-covid-19-testing/>.

- 8) Has CMS received any outreach from facilities about the use of hydroxychloroquine? If so, please describe that outreach and provide any correspondence associated with it.
- 9) What, if any guidance, has CMS given facilities on the use of hydroxychloroquine if it is prescribed by an attending physician not associated with their nursing home?
- 10) Has CMS reviewed state survey or inspection reports to determine whether nursing homes that were treating residents for COVID-19 received adequate consent for that treatment?
- 11) Has CMS opened any investigations into the use of hydroxychloroquine by nursing homes or taken any enforcement action against such homes? If so, please provide the number of investigations and enforcement actions, the names of the facilities involved, and any other relevant findings or information.
- 12) Is CMS aware of any other drugs being used by nursing homes to prevent or treat COVID-19? If so, please identify those treatment regimens and the facilities implementing them.
- 13) What protocols must nursing homes put in place to ensure that residents or their guardians provide knowing consent in advance of treatment? How are these protocols enforced? How are nursing homes held accountable when these protocols are not in place or are not followed?

Given the urgency of this matter we request this information as soon as possible, but in no event later than September 10, 2020. We look forward to your prompt attention to this matter.

Sincerely,

/s/

Robert P. Casey, Jr.
United States Senator

/s/

Ron Wyden
United States Senator

/s/

Elizabeth Warren
United States Senator

CC: Department of Health and Human Services, Office of Inspector General
Food and Drug Administration