CHARLES E. SCHUMER **Majority Leader**
NEW YORK

United States Senate

WASHINGTON, DC 20510-3203

June 8, 2022

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue
Washington, D.C. 20201

Dear Administrator Brooks-LaSure:

I write to ask that CMS revise a sub-regulatory guidance issued in 2015 to protect the Critical Access Hospital (CAH) status of more than seventy rural providers nationwide, including nine in New York State. In your March 31, 2022, letter to the Honorable Antonio Delgado regarding this same issue, you indicated that the Centers for Medicare and Medicaid Services (CMS) would undergo a formal notice and comment rulemaking process to formalize the eligibility criteria for CAH status. Rather than go through a time-intensive rulemaking process, I ask that CMS simply revise Chapter 2 of the State Operations Manual (SOM) to reflect the pre-2015 requirements for CAH eligibility and advise state surveyors not to apply the guidance until the revision is complete.

As you know, CAHs were created by the Balanced Budget Act of 1997 and allow smaller rural providers with the designation to receive greater financial reimbursement for servicing Medicare, Medicaid and Tri-Care patients, access to grant funding and other resources – all designed to keep otherwise financially vulnerable rural hospitals viable. In order to qualify as a CAH, a hospital must be – among other qualifications – a certain distance from another hospital by either a primary or secondary road and provide around-the-clock emergency services. Before June 2015, CMS regulations stated that a CAH hospital must be at least 35 miles from the nearest hospital by "primary road", defined as any road in an interstate system or a US-numbered highway, or at least 15 miles in areas with mountainous terrain or only "secondary roads", defined to include single lane state routes. Alongside New York's eighteen CAH's, there are 1,353 CAHs nationwide as of 2021 under these definitions.

However, on June 26, 2015, CMS sent a memorandum (S&C: 15-45-CAH) to State Survey Agency Directors, who evaluate CAH eligibilities in each state, advising them of several policy changes regarding CAH status. On page 3 of the memorandum, CMS changes the definition of primary road to include any road that is in the National Highway System, which would include NYS routes that are a part of the System. This expansion of the definition of "primary road" could result in dozens of CAHs in multiple states, including nine in New York State, not meeting the revised distance requirement.[1] Following the issuance of that first memorandum, CMS included this new definition of the "primary road" in Chapter 2 of its State Operations Manual, further solidifying this harmful policy change.

It is very troubling that such a substantial policy change that impacts the care of thousands of rural Americans, was made without going through the proper notice and comment rulemaking procedure. This is a position that CMS has traditionally agreed with. In fact, on October 31, 2019, the Office of the

[1] Not all of these CAHs would necessarily lose their status. At least some of these CAHs are necessary providers that are exempt from having to meet the distance requirements by statute. We do not know how many of these 77 CAHs are necessary providers.

General Counsel (OGC) advised CMS that "any Medicare issuance that establishes or changes a 'substantive legal standard' governing…payment for services…, must go through notice-and-comment-rulemaking." OGC furnished this guidance in response to adverse litigation against the Secretary in *Azar vs. Allina Health Services*.[2] According to the standard set in that OGC advisement, expanding the definition of "primary road" through a memorandum should also constitute a substantive legal standard changed through a sub-regulatory procedure that ought to have been done through notice and-comment rulemaking.

Prior to the start of the public health emergency (PHE) at least one hospital we know of was closed due to the enforcement of this policy change. Thankfully, CMS has not enforced this policy change during the PHE, although it remains on the books ready for enforcement. In your March 31, 2022, letter to the Honorable Antonio Delgado, CMS indicated that the agency has delayed using the 2015 distance criteria for CAH recertification for the duration of the PHE. I am thankful that the agency agrees that it is inappropriate to pull critical funding streams from rural providers while the COVID pandemic continues to place enormous public health and financial strains on these providers. However, I am concerned your letter implies that enforcement of the sub-regulatory guidance may commence at the end of the PHE prior to CMS undergoing rulemaking. I respectfully request that CMS confirm that it will not enforce the current sub-regulatory guidance changing the definition of primary road in its State Operations Manual while the agency considers potential notice and comment rulemaking.

Further, I request that CMS revise its State Operations Manual to restore the pre-June 26, 2015 definition of "primary road". As it stands today, the current policy after the definition change is not enforceable as the post-June 26, 2015, definition of primary road changed a substantive legal standard without being adopted through notice and comment rulemaking.

Restoring the definition of primary road back to the pre-June 26, 2015, language in the State Operations Manual will make clear to State Survey Agency Directors the currently applicable policy that may be enforced when either certifying a new CAH or recertifying an existing CAH. I further ask that CMS provide State Survey Agency Directors with a memorandum analogous to the one on June 26, 2015, advising them of the change to the State Operations Manual and their obligation to apply the pre-June 26 2015 guidance.

Sincerely,

Charles E. Schumer
United States Senator

Encl: CMS Rep. Antonio Delgado CAH Response Letter, March 31, 2022

[2] (https://d1198w4twoqz7i.cloudfront.net/wp-content/uploads/2019/12/05141151/CMS-Memo_Impact-of-Allina-on-Medicare-Payment-Rules.pdf).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

March 31, 2022

The Honorable Antonio Delgado
United States Congress
Washington, DC 20515

Dear Representative Delgado:

Thank you for your letter regarding the eligibility criteria for Critical Access Hospital (CAH) designation, specific to evaluating the distance between CAHs as described in Chapter 2 of the State Operations Manual. I appreciate your bringing these concerns to our attention, as well as our continued dialogue on this important issue to ensure access to safe and quality health care in rural communities.

The Centers for Medicare & Medicaid Services (CMS) has delayed using the 2015 distance criteria for the purposes of recertification for the duration of the Public Health Emergency. Now CMS plans to go through notice and comment rulemaking to obtain the benefit of public comment with respect to the CAH distance requirements. I have asked the CMS team to keep you posted on any CMS rule soliciting comments on this issue.

Thank you again for your letter on this critical issue for Medicare beneficiaries residing in the State of New York. Should you or your staff have questions, please contact the CMS Office of Legislation.

Sincerely,

Chiquita Brooks-LaSure