We write to express our extreme disappointment in the decision by the Centers for Medicare & Medicaid Services (CMS) to release the attached guidance that appears to be an attempt to make it harder for the Biden Administration to end the illegal and harmful Medicaid waivers that you have championed. While the letters claim to establish the procedures the Trump Administration will follow to withdraw approval of section 1115 demonstrations, they are nothing more than a hastily-drafted, transparent attempt to tie the hands of the Biden Administration for at least nine months, and entrench your shameful Medicaid legacy after your time as CMS Administrator has ended.

While the letters claim to be a “letter of agreement,” this meaningless linguistic flourish cannot discount the fact that they are plainly guidance documents. CMS clearly has the authority to establish the procedures it will follow to withdraw approval for 1115 demonstrations. Regulations at 42 C.F.R. 431.420(d)(3) state “the terms and conditions for the demonstration will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities.” Accordingly, CMS has two options for establishing terms and conditions such as those established in the letter; it can do so by amending the 1115 demonstration approval’s special terms and conditions (STCs), or through rulemaking. However, each of these options includes certain procedural requirements that would have been impossible to carry out in the little time you have left. Accordingly, it appears these letters are an attempt by CMS to make an illegitimate end-run around its existing regulations and it cannot stand.

Despite your efforts to camouflage these letters as something novel, a simple examination of their function reveals they are impermissible sub-regulatory guidance. Sub-regulatory guidance is largely a self-evident term – it is guidance, not issued through regulations, that provides parties with clarity as to how an agency will conduct itself in certain situations. Through these letters, CMS is attempting to establish new procedures that would govern how it withdraws approval of 1115 demonstrations. Identical copies were sent to each state with an approved 1115 demonstration so that the same rules will apply nationally. There is no doubt that this is sub-regulatory guidance.

Unfortunately for CMS, sub-regulatory guidance cannot override or repeal existing regulations. That can only be done through rulemaking. Existing regulations clearly state that the terms and conditions of each waiver will detail the notice and appeal rights for a state in the
event of a termination, suspension, or withdrawal of a waiver. The regulations do not establish an alternative process whereby CMS can establish the notice and appeal rights through sub-regulatory guidance, or so-called “letters of agreement.” Accordingly, these letters are impermissible under existing regulations and states cannot rely on the assertions or supposed commitments that they contain.

This Administration has repeatedly flouted the Social Security Act to pursue its reckless and cruel Medicaid agenda. It is no surprise that in your final days as CMS Administrator, you would once more exceed your legal authority in an attempt to force your radical ideological agenda onto more than 76 million Medicaid beneficiaries. Fortunately, as with your previous efforts to undermine the Medicaid statute, these letters plainly violate federal law and, therefore, cannot stand. We respectfully request that you rescind these letters immediately and allow the nation, and the Medicaid program, to heal from your repeated attempts to undermine this critical program.

Sincerely,

Frank Pallone, Jr.
Chairman
House Committee on Energy and Commerce

Ron Wyden
Ranking Member
Senate Committee on Finance
January 4, 2021

State Medicaid Director
Agency
Address

Dear State Medicaid Director:

Your state currently operates at least one Medicaid section 1115 demonstration. These demonstrations have proven to be a cornerstone of state innovation from which new best practices can emerge and next generation program design be fostered. They represent one of the most critical elements of our commitment to state flexibility and building a state and federal partnership centered on accountability and results.

By their nature, section 1115 demonstrations represent a contract between the state and federal government, governed by established terms and conditions and only approved after a determination by the Secretary of the Department of Health and Human Services (HHS) that such a demonstration would advance the objectives of the Medicaid program. In the rare event that CMS makes a determination that it must terminate, amend, or withdraw waiver authority, the standard terms and conditions in each demonstration generally provide for a process in which CMS will notify the state in writing and afford the state an opportunity to request a hearing prior to the effective date.

Your terms and conditions describe this process at only a high level, without describing the advance notice or the specific timeline in which such an opportunity to be heard would occur. While a decision to terminate or withdraw waiver authority would likely only be made as a last measure, states have the right to due process over that decision as well as adequate notice to prepare to transition their programs to a new state of authority. That is why I am sending to you today a letter of agreement outlining additional details of the process which CMS commits to applying prior to the effective date of any amendment or withdrawal of a demonstration.

By signing this letter of agreement, you are agreeing to abide by this process should CMS in the future take any such relevant action against an existing 1115 demonstration operating in your state. If you would like to commit to adhering to this process, I ask that you return this agreement, signed by the state Medicaid director or appropriate authority, as soon as possible. Please send to me directly or email the signed agreement to 1115demorequests@cms.hhs.gov.

Sincerely,

Seema Verma

Enclosure
CMS regulations state that each Section 1115 demonstration’s Terms and Conditions “will detail any notice and appeal rights for the State for a termination, suspension or withdrawal of waivers or expenditure authorities.” 42 CFR § 431.420(d)(3). While the precise language in each demonstration’s Terms and Conditions varies slightly, these documents set forth only a general outline of the procedure to apply, for example: “CMS will promptly notify the State in writing of the determination and the reasons for the amendment and withdrawal, together with the effective date, and afford the State an opportunity to request a hearing to challenge CMS’ determination prior to the effective date.” This letter agreement sets forth the procedures that CMS commits to applying prior to the effective date of any amendment or withdrawal of a demonstration.

If CMS determines that it will either (1) suspend or terminate a demonstration in whole or in part because the State has materially failed to comply with the terms of the demonstration project, or (2) withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes, see 42 CFR § 431.420(d)(1)–(2), CMS will promptly notify the affected State in writing of its determination and the reasons for the suspension, termination, amendment, or withdrawal. CMS will also provide an effective date for its determination and a schedule for a hearing to challenge CMS’ determination.

In order to ensure that affected states have adequate notice and opportunity to be heard, CMS shall make the effective date for its determination no sooner than 9 months after the date on which CMS transmits its determination to the affected State. The hearing and associated briefing shall adhere to the following schedule:

- Within 15 days of the date of CMS’ determination, the affected State shall provide notice in writing to CMS that it disagrees with CMS’ determination and plans to invoke its right to a hearing as part of a preliminary appeal.
- Within 90 days of the date of CMS’ determination, the affected State shall submit a written brief to CMS outlining the bases for its disagreement.
- Within 90 days of the date the State submits its written brief, CMS shall send a written response to the affected State responding to the major arguments raised by the State.
- Within 60 days of the date that CMS sends its written response, the State shall submit a written rebuttal responding to the major arguments raised by CMS.
- Within 45 days of the date that the State sends its written rebuttal, CMS shall hold a hearing and provide the State with an opportunity to be heard regarding its disagreement with CMS’ determination.
- Following the hearing, CMS shall issue a written decision either modifying or finalizing its initial determination.
The decision resulting from this preliminary appeals process shall be appealable to the Departmental Appeals Board using the procedures at 45 CFR Part 16. See Appendix A to 45 CFR Part 16, C.(b). Monetary damages cannot remedy a breach of this preliminary appeals process. Any breach constitutes irreparable harm and final agency action.

The preliminary appeals process set forth above applies to the following demonstrations:

**State Demonstration Plan**

_____________________________________________________________
State Medicaid Director
Agency
State
Date: ____________________

_____________________________________________________________
Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Date: ____________________