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VETERANS' AFFAIRS

September 17, 2021

Secretary Xavier Becerra
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Secretary Becerra,

Health care providers across the country rely on highly-effective monoclonal antibody (mAb) drugs to treat COVID patients. These life-saving drugs reduce hospitalizations. I am concerned by recent HHS action that adds multiple levels of bureaucracy to the mAb ordering process.

Before HHS announced it would intervene in the provider-supplier ordering relationship of mAb drugs, Alabama providers ordered treatments directly with drug suppliers. HHS and suppliers alike have assured my office that there is no supply issue, so the fundamental question is why HHS is now choosing to get involved.

HHS will now mandate providers appeal to their state health departments for mAb orders. State health departments must then look to HHS to tell them exactly how many doses they are permitted to receive that particular week, dependent on a formula that HHS has yet to explain in specific detail. In the days since this change was reported, my office has been inundated with pleas for help from providers whose mAb orders were not fulfilled. This announced change in policy is already affecting lives – patients are being turned away who otherwise could be treated with mAb drugs. It is imperative that HHS explain why these changes come at such a critical time and why states that most need these treatments the most are being targeted.

My concern lies not just in the new program HHS has dictated – which will also require state officials to hire additional staff to manage, during an ongoing workforce shortage – but in the sudden manner these changes were announced, and states that have been singled out.

It is my understanding that seven states (Alabama, Florida, Texas, Mississippi, Tennessee, Georgia, and Louisiana – notably, majority-Republican states) were told that they would likely have their supply of mAb drugs reduced by the new protocols. While I certainly understand that these states may have lower vaccination and higher hospitalization rates than others, it stands to reason that they would benefit more from a steady and direct supply of mAb treatments to keep hospitalization rates down.

Furthermore, states with lower vaccination rates should not be singled out or have access to life-saving treatments potentially reduced because they have a higher population of unvaccinated COVID patients. Patients benefitting from mAb treatment already have COVID – by the time they seek medical attention, they are past the point of being helped by a vaccine. Therefore, restricting access to mAb treatments available to this population does much more harm than

good. Simply put, the Administration is risking lives and wasting critical hospital resources by limiting this valuable treatment option to providers.

Given the concerns listed above and the seemingly political nature of this decision, please provide responses to the following questions:

- How did HHS reach the decision to take control of mAb supply and insert itself into the ordering and acquisition process?
- What metrics were used to determine which states' supply might be reduced?
- Under this new program, would states be forced to reroute their supply of mAbs to another state that might be experiencing a spike or outbreak that week?
- Is HHS maintaining a stockpile of mAbs to deploy in case of a severe outbreak?
- HHS has said that it will determine the weekly amount of mAb treatments each state and territory receives based on COVID-19 case burden and mAb utilization. What exact formula is then used to determine actual number of doses permitted for distribution?
- How are providers being required to report this case burden and mAb utilization data, and how can HHS ensure this doesn't add undue burden onto overwhelmed hospital staff?
- Currently there is ample supply of mAb. Does HHS have evidence to support the notion that a supply shortage is imminent?
- Aside from urging increased vaccination rates in Alabama, what can providers do to prove to the federal government that they need unrestricted access to orders of mAb treatments?
- How can constituents of targeted states have confidence that the Administration is not just withholding mAb drug orders to strongarm states into additional vaccine mandates?

Simply put, I am concerned that by seizing control of this critical supply chain, HHS will exert more power over states by restricting access to these treatments. The ability to withhold access is problematic in that it allows unelected bureaucrats at HHS to put undue political pressure on states to comply with whatever additional COVID-related mandates they deem appropriate.

Physicians and health care providers in the state of Alabama remain committed to working together to fight COVID-19 in our communities, just as they have been since the beginning of the pandemic. They simply ask for the unrestricted freedom and ability to continue the fight by using every available tool in the toolbox – and monoclonal antibody drugs remain absolutely critical in that effort.

Thank you for your attention to this important matter. I look forward to your response.

Sincerely,