ARKANSAS DEPARTMENT OF HUMAN SERVICES

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3415-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Public Comment Submission for CMS-3415-IFC
Medicare and Medicaid Programs; Omnibus COVID 19 Health Care Staff Vaccination

The Arkansas Department of Human Services (DHS) opposes this interim final rule through which CMS is imposing an oppressive, wide-ranging vaccination mandate as a health and safety standard for healthcare providers. DHS opposes this rule because of the harm it will inflict by exacerbating already-significant staffing challenges for healthcare facilities serving the most vulnerable.

DHS and its clients are particularly at risk from this rule because of the seven state-owned healthcare facilities that DHS directly operates – a psychiatric hospital, a skilled nursing facility with the only ventilator unit at such a facility in the state, and five intermediate care facilities for individuals with intellectual disabilities. Five of these facilities are in more rural areas of Arkansas. By directly threatening the ability of DHS to maintain the adequate staffing that is essential to protecting the health and safety of the residents of these facilities, the overall harm that will be inflicted by this interim final rule will far exceed any benefit that may accrue in the battle against COVID-19.

CMS has acknowledged concerns that health care workers will choose to leave their jobs rather than receive the vaccine. Arkansas already has a low vaccination rate among health care providers. The State has provided financial incentives and extensive information to promote the vaccines among our health care workers, but vaccine hesitancy remains a problem. Among the seven facilities operated by DHS, the overall vaccination rate is only 63%. These figures are consistent with CMS' own recognition that "vaccination rates are disproportionately low among nurses and health care aides" in rural locations and that "early indications are that rural hospitals are having greater problems with employee vaccination."

It is likely that some of Arkansas' health care workers will choose to leave their positions if they are forced to make a choice between their jobs or the vaccine. Such a large exodus of health care workers will have catastrophic effects on the health care system in Arkansas, which is already stressed by staffing shortages. For example, between July 1, 2020, and June 30, 2021, the seven facilities operated by DHS experienced staff attrition rates between 26% and 79%, with four of the facilities

having an attrition rate of 50% or higher. These rates represent increases between 25% and 76% over the prior year, indicating what a severe impact the COVID-19 pandemic has had on healthcare staffing. Increased pay for these direct care positions has not made a significant impact on attrition. Adding a vaccination mandate will only make the staffing situation worse.

CMS' prediction that staffing deficiencies "might be offset by persons returning to the labor market who were unwilling to work at locations where some other employees are unvaccinated" does not make logical sense in a state with such high numbers of health care workers refusing to take the vaccine. There are not enough trained health care workers in the state to replace staff who leave. Facilities will have very few options available to them to make sure their clients and patients' needs are met. Moreover, if facilities are forced to bring in lesser-trained temporary health care staff or if remaining staff members are forced to work outside of safe patient/staff ratios to cover for the lack of health care staff, the safety of our clients will be at risk, negating any positive gains that could possibly come from the mandate. This Rule puts our patients and clients in danger.

CMS has not properly considered the impact this rule will have on the vulnerable populations in states such as Arkansas, which rely heavily on rural hospitals and facilities to provide services. And CMS has failed to explain why it is imposing a vaccination mandate that includes nursing home staff members only days before CMS completely eliminated visitation restrictions in nursing homes. In Memorandum QSO-20-39-NH as revised on November 12, CMS determined that the relatively high vaccination rate of nursing home staff and residents meant that unrestricted visitation no longer poses "a clinical health and safety risk to residents." On the one hand, CMS has determined that unlimited direct contact with residents by unvaccinated visitors is not a clinical health and safety risk. But CMS has also determined that the health and safety risk posed by unvaccinated nursing home staff – regardless of how long they work or whether they even encounter residents – is so high that it justifies mandatory vaccination. These two determinations utterly contradict one another and cannot be reconciled.

CMS could avoid many of the issues identified above by including a testing alternative to the vaccination requirement. The Arkansas General Assembly recently approved Acts 1113 and 1115 of 2021, which establish exemptions for employees from COVID-19 vaccination mandates, with an exemption process based on testing or other proof of immunity. A negative antigen detection test result or molecular diagnostic test result no more than one (1) time per week showing that the employee is not positive for COVID-19 would also be an effective means of preventing positive COVID-19 cases from going unchecked within the health care community. Further, such a provision is in line with the OSHA rule that was released prior to CMS releasing this ICF, which shows that the Biden Administration does consider testing to be an effective means of controlling the virus. CMS should also consider other alternatives for testing that help to lower the costs of prevention including allowing employees to provide proof of immunity to COVID-19 or its variants by presenting evidence of the presence of antibodies, T cell response, or proof of a positive COVID-19 test on the basis of 2 times per year, at least 6 months apart. If CMS chooses to move forward with the vaccination mandate, DHS asks that CMS allow for exemptions developed in state law such as those created by Arkansas Acts 1113 and 1115.

Although DHS is primarily concerned about the impact of the vaccination mandate on healthcare staffing, DHS also strongly objects to the use of Conditions of Participation to carry out this new mandate. As CMS acknowledged, this mandate goes beyond the established use of CoPs. If allowed to stand, it will set a precedent for future Administrations to use the power of the federal purse to compel compliance with a policy outside normal procedures. It is not difficult to imagine what other controversial policies that impact public health may be swept under the heavy hand of an agency that controls over $1 trillion in spending each year.

DHS further objects to the use of an Interim Final Rule, that CMS seeks to implement a controversial policy outside of the parameters of rulemaking required by the Administrative Procedures Act and the Social Security Act. First, CMS has failed to demonstrate good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. CMS should abide by the proper APA procedures for rule promulgation. CMS has attempted to say that the nature of the pandemic necessitates moving forward with this interim final rule without the mandated 60-day public comment period that is required under § 553(b)(B) of the APA (5 U.S.C. § 553) and § 1871(b)(2)(C) of the Social Security Act (42 U.S.C. § 1395hh(b)(1). However, the Delta variant has been present in the U.S. population since May and at least one of the vaccines has been FDA approved since August. During that time CMS did not feel the Delta variant created such a risk that a rule should be immediately developed. CMS is giving Medicare and Medicaid providers sixty days to fully implement the IFC rule, although it does not take sixty days for a person to become fully vaccinated. These timelines do not match to the supposed need to skip the comment period.

Second, CMS has failed to prepare and make available for public comment an initial regulatory impact analysis as required under 42 U.S.C. § 1302(b)(1). Section 1302(a) grants the Secretary of Health and Human Services the authority to "make and publish rules and regulations, not inconsistent with [the Social Security Act] as may be necessary to the efficient administration of the function with which [it] is charged under [the] Act. However, subsection (b) requires the Secretary to analyze and make public an initial regulatory impact analysis that describes "the impact of the proposed rule or regulation" on rural hospitals whenever the rule or regulation proposed "may have a significant impact on the operations of a substantial number of small rural hospitals." CMS acknowledges that this rule may have such impact and thus should have completed this initial analysis. No analysis has been provided; therefore, CMS cannot state, and stakeholders cannot know the projected potential impact this rule has on small entities.

Third, CMS did not consult with the appropriate State agencies and recognized national listing or accrediting bodies before publishing this interim final rule in accordance with 42 U.S.C. § 1395z. Had CMS consulted with the appropriate State agencies it could have been made aware of the issues described above and worked with these agencies to come up with a solution that would not endanger the welfare of our State's most vulnerable populations.

Finally, the Rule may place providers in danger of running afoul of the False Claims Act. 21 U.S.C.S. § 3729 et seq. This Rule puts providers, including states as providers, in a catch-22 situation. In submitting a claim to Medicare or Medicaid, a provider attests it is in compliance with all federal rules. Every day, health care providers must work within a world of risk management and imperfect knowledge. But with this rule, CMS is forcing providers to attest to something that cannot be known

and offers no alternative to mitigate risk. Under the False Claims Act any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person. Medicaid providers are not able to bill for services that are provided not in accordance with Medicaid regulations. Under this interim final rule, providers and suppliers are required to know if contractors and other employees who are not regular employees of their facilities, but who are employees of other companies, are vaccinated. It is nearly impossible for one health care provider to keep up with the health status of the employees of all its contractors, suppliers, and others who come in and out of contact with the provider's employees who may encounter other employees or beneficiaries. This leaves open the real possibility that a provider will inadvertently bill for services on a date that an employee is in contact with an unvaccinated contractor, making the provider, who is out of compliance because of the contractor, violate 31 U.S.C. § 3729. DHS respectfully requests that CMS and the HHS Office of Inspector General provide a joint written opinion on the applicability of 31 U.S.C. § 3729 to this rule.

Sincerely,

Cindy Gillespie
Secretary of Human Services

cc: Governor Asa Hutchinson
Hon. Jimmy Hickey, Jr., Arkansas Senate President Pro Tempore
Hon. Matthew J. Shepard, Speaker of the Arkansas House of Representatives
Hon. Terry Rice, Senate Co-Chair, Arkansas Legislative Council
Hon. Jeff Wardlaw, House Co-Chair, Arkansas Legislative Council
Hon. Cecile Bledsoe, Chair, Arkansas Senate Public Health, Welfare & Labor Committee
Hon. Jack Ladyman, Chair, Arkansas House Public Health, Welfare & Labor Committee