AAAHC

ACCREDITATION ASSOCIATION
for AMBULATORY HEALTH CARE, INC.

January 4, 2022

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

Via Electronic Submission at *http://www.regulations.gov*

RE: CMS-3415-IFC
RIN 0938-AU75

Dear Administrator Brooks-LaSure,

The Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) greatly appreciates the opportunity to submit comment to the Centers for Medicare & Medicaid Services (CMS) regarding the Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

AAAHC is a private and independent 501(c)(3) non-profit accreditation organization formed in 1979. Since its inception, AAAHC has promoted a voluntary, peer-based, and educational survey process to advance patient care. These values hold true today, as embodied in our mission statement: *Improving health care quality through accreditation*. With more than 6,100 accredited organizations in a variety of ambulatory health care settings, AAAHC is a leader in developing standards to advance and promote patient safety, quality care, and value for ambulatory health care through its accreditation programs, education, research, and other resources. Currently, more than 1,000 ASCs are committed to excellence through AAAHC Accreditation under the CMS deemed status program, making AAAHC the leading Medicare-approved, non-hospital accreditation organization in the country. AAAHC also provides accreditation services to the United States Coast Guard ambulatory health centers, Federally Qualified Health Centers (FQHC) that receive funds from United States Health Resource and Services Administration (HRSA), Indian Health Services funded health centers, and Correctional Healthcare units under the United States Federal Bureau of Prisons (BOP). Other AAAHC-Accredited Organizations include Community Health Centers, Indian Health Centers, Student Health Centers, Medical Group Practices, and Office-based Surgery Procedure Centers.

In this comment, we address our concerns regarding the above-captioned rule as it applies to ASCs and FQHCs.

5250 Old Orchard RD, STE 200
Skokie, Illinois 60077
TEL 847.853.6060
FAX 847.853.9028
www.aaahc.org
info@aaahc.org

1. Collection of Information Requirements (ICRs), page 61586

A. ICRs Regarding the Development of Policies and Procedures for ASCs § 416.51(c) "COVID-19 Vaccination of Staff", page 61589

and

N. ICRs Regarding the Development of Policies and Procedures for RHCs and FQHCs § 491.8(d) "COVID-19 Vaccination of Staff", page 61596

Policies and Procedures

CMS Requirement: In this Interim Final Rule, CMS is requiring providers and suppliers to develop policies and procedures that ensure all staff are vaccinated, staff vaccination statuses are tracked and maintained, and a contingency plan is in place for staff who are not yet fully vaccinated.

CMS Burden Calculation: For ASCs, CMS has calculated the burden to include eight (8) hours for the research and development of policies and procedures and two (2) hours for administrator approval of the policies and procedures, per ASC. For RHCs and FQHCs, CMS has calculated the burden to include eight (8) hours for the research and development of policies and procedures, two (2) hours each for review and revisions from a physician, nurse practitioner, and physician assistant, and one (1) hour for medical director approval of the policies and procedures, per RHC or FQHC.

CMS Solicits Comment on the need for the information collection and its usefulness in carrying out the proper functions of the agency; CMS Solicits Comment on the accuracy of CMS's estimate of the information collection burden.

While AAAHC supports CMS in its health care oversight role and appreciates the CMS interest in protecting patients through a vaccine requirement, AAAHC believes, because the COVID-19 situation is so dynamic, that today's burden calculation will change, and has certainly changed since the Interim Final Rule (IFR) was first published. AAAHC is concerned that adoption will set a precedent for future reactive rulemaking in rapidly evolving environments that, like this rule, disregards the burden on systems already functioning to effectively mitigate transmission of communicable diseases and environmental hazards, including COVID-19. As such, AAAHC does not support CMS in this rulemaking and believes that it is necessary to refocus the COVID-19 mitigation approach systematically, avoiding additional burden on an already stressed health care system. AAAHC believes that when facility operations are excessively focused on rapidly shifting compliance models, the result is the diversion of attention and resources away from patient care and safety.

The AAAHC Standards already require facilities to demonstrate evidence of a staff vaccination program, an infection prevention program with training, policies, and procedures for the protection of health care workers from biologic hazards, and compliance with occupational health and safety. Our CMS-approved compliance structure allows ambulatory surgery facilities to choose the procedures and mitigation strategies that best fit their organization and unique patient population. Without evidence or data to the contrary, when an organization chooses to participate in the AAAHC accreditation process, which, in some areas exceeds the CMS conditions for coverage, AAAHC-accredited organizations and their governing bodies commit to ongoing compliance with patient safety and quality standards that already address mitigation of communicable diseases such as COVID-19.

With the breadth of standards employed by accreditation organizations, AAAHC believes that if CMS updates the burden analysis, it should consider the burden on not only facilities and their staff, but on the whole system. Additional costs for accreditation organizations to train staff and surveyors on continual regulatory changes, to deploy additional educational programs for facilities, and to hire additional staff to assist with the changing rules are costs that will be passed down to facilities and will ultimately be borne by patients.

Further, accreditation decision making will be inherently flawed where the same standards are not equally applied to all organizations. As a result of the state limitations in place after the two federal district court enjoinments of the CMS IFR and the December 28, 2021 CMS AO QSO, AAAHC will face significant challenges in comparing standards compliance over time where facilities are not subject to the same standards. The burden faced by facilities in the states in which enforcement of the CMS rule is enjoined will be significantly less than those in the states in which CMS is directing enforcement creating a potential imbalance in the quality of care and future measurement of the quality of care provided by ambulatory surgical facilities in one state when compared to those in another since they will be surveyed against different requirements. AAAHC is further concerned that patients will be placed at higher risk when receiving care in facilities in the states in which vaccination is required under the IFR, especially when the facilities exist in high COVID-19 and already stressed transmission states or where the facilities may not have extensive resources to immediately implement the rule and therefore must choose between investing in direct patient care or compliance with requirements that have constantly changed since January of 2020 when COVID-19 was first identified in the United States.

We are further concerned by the increased burden on accreditation organizations required in the most recent CMS AO QSO that requires compliance within 30 (thirty) days of issuance of the memorandum. We are troubled that CMS appears to have disregarded the current impact of COVID-19 on all employers, including accreditation organizations. While AAAHC survey operations continue to move forward effectively and efficiently, we are also facing mitigation of staff COVID-19 transmission as well as staff absences due to community-acquired infection, impacting the ability to implement new initiatives or update existing operations at the same rate that CMS can release and direct new guidance. We urge CMS to reconsider the timeline for compliance as noted below.

CMS Solicits Comment on the quality, utility, and clarity of the information to be collected.

While AAAHC understands that CMS intends to prevent transmission of COVID-19 to patients, and as described above, supports requirements for policies and procedures that mitigate transmission of communicable diseases within facilities, we question whether documentation and information collection of requiring vaccination status would have correlation to transmission reduction within an organization. Documentation of ambulatory health care facility workers vaccination alone cannot by itself mitigate transmission where an organization does not have other mitigation strategies in place for all individuals who enter the facility, such as mask requirements, disclosure of COVID-19 infection, or validation of vaccination status.

Regarding the utility of the information to be collected, as an accreditation organization, AAAHC is acutely aware of the need for validation of data—it is the basis of the onsite portion of an accreditation survey that provides the final basis for rendering accreditation decisions, and we will certainly verify existence of policies and procedures for compliance with this rule where required. However, AAAHC respectfully recommends that where data collection is required, that CMS share the reasoning behind the data collection and the purpose for requiring the data collection. As previously noted, facilities are already expected to comply with the standards noted above that function holistically to mitigate the spread of communicable diseases and biohazards. We are especially concerned with the potential for these policies and procedures to distract from other ongoing health care issues of concern, such as the opioid epidemic that continues across the United States, and we request guidance from CMS regarding the best way to survey for these new standards where our current processes do not account for additional standards or a lengthier survey that could lead to additional fees assessed to the facilities.

CMS Solicits Comment on recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

AAAHC supports CMS in any efforts to reduce the information collection burden on the affected public. As previously noted, systems and standards already exist to validate organizational compliance with policies and procedures. Again, a concern is the increased survey time that surveyors will face to evaluate COVID-19 specific policies and procedures and the cost burden this will add to the facilities. In years past, various agencies have established different workgroups that included representatives from accreditation organizations. In lieu of constantly updated regulatory requirements, AAAHC recommends that CMS reestablish the Infection Prevention and Control Workgroup made up of a variety of stakeholders, including accreditation organizations that can identify on a yearly basis focused initiatives that could be balanced against other survey obligations with CMS guidance.

Documentation and Storage

CMS Requirement: In this Interim Final Rule, CMS is requiring providers and suppliers to track and securely maintain documentation of staff vaccination status.

CMS Burden Calculation: For ASCs, RHCs, and FQHCs, CMS has calculated the burden to include five (5) minutes per employee or staff member.

CMS Solicits Comment on the need for the information collection and its usefulness in carrying out the proper functions of the agency; *CMS Solicits Comment on the accuracy of CMS's estimate of the information collection burden; CMS Solicits Comment on the quality, utility, and clarity of the information to be collected; CMS Solicits Comment on recommendations to minimize the information collection burden on the affected public, including automated collection techniques.*

While AAAHC is aware that facilities may already collect health care worker vaccination status in a variety of different ways, without a validation tool, the data cannot be actionable nor, at the very least, claimed to be accurate. Depending on the collection method used, there is often an aspect of human error. Several vaccination validation software tools on the market exist; however, state agencies, facilities, and other groups are not using the same databases. If CMS requires data collection for a specific purpose, we highly recommend that any data collection be validated for the data to be actionable. Data validation, unfortunately, would add a significant cost burden onto each of the ambulatory care facilities, and therefore we do not think that this is a requirement necessary to carry out the CMS mission of ensuring patient safety.

Even if a validation tool that presents no burden exists, the value of the information collection within a particular organization would be very limited and extremely difficult to establish a correlation between the goal to reduce staff transmission and transmission to patients since the information collection within the facility would not account for individual lifestyles and risk of transmission or other community-acquired sources of COVID-19 transmission. The AAAHC position is that this data collection and compliance review is an unnecessary burden to require collection of this data for purposes of participation in Medicare and that the percentage of compliance in the collection of unvalidated data as directed in QSO 22-07-ALL does not indicate an immediate threat to patient health or safety. Imposing condition-level findings or immediate jeopardies on vaccine non-compliance could result in non-accreditation or loss of CMS certification for providers and further reduce access to care when care is most greatly needed during the pandemic.

2. Anticipated Cost of Interim Final Rule with Comment Period, page 61604

Anticipated Cost Analysis 1: CMS anticipates that providers and suppliers may include staff counseling and education with their implementation of this Interim Final Rule but is unable to estimate the burden; Anticipated Cost Analysis 2: CMS anticipates that providers and suppliers may include the use of rewards and incentives with their implementation of this Interim Final Rule but is unable to estimate the burden. Anticipated Cost Analysis 4 and 5: CMS states that the most important inducement for staff vaccination will be fear of job loss and that staff will have a reduced ability to change employers if all similar providers and suppliers are also mandating vaccination; Anticipated Cost Analysis 6: CMS anticipates that any staffing and service disruptions that providers and suppliers may face due to staff refusals of the mandatory vaccination will be offset by the reduced illness and reduced quarantine of remaining staff members.

AAAHC believes it is not possible for any facility to implement these requirements without educating and offering opportunities for counseling to staff. Behavioral health is currently one of the most resource-challenged areas right now and to add additional burden to the behavioral health system as a result of new employer requirements places further strains on this specialty. As noted previously, there will be an additional burden on AOs and state agencies that is not accounted for in this IFR. COVID-19 guidance changes on a day-to-day basis and in our own experience as an employer, we find ongoing development of updated communications relating to COVID-19 developments necessary but burdensome and time intensive to ensure optimal operations and support our employees with updated information.

While AAAHC agrees that the use of rewards and incentives may be necessary to obtain staff buy-in, AAAHC is concerned about a position that fear of job loss is an inducement to compliance with this vaccination rule. As an accreditation organization, we are concerned with requirements that could cause job dissatisfaction and stress in an already stressed system. Negative reaction to this requirement could potentially trickle down to impacting the health, safety, and welfare of patients as well as the quality of patient care received in areas such as reduced staff-to-patient ratios and general employee burn-out and fatigue which can lead to carelessness. Where there are alternatives that already exist, we strongly urge CMS to consider those alternatives.

3. Other Effects, page 61612-Regulatory Flexibility Act

Regulatory Flexibility Act Analysis 1: CMS recognizes that most providers and suppliers qualify as small entities under the RFA but provides that "significant effect" is defined as either an increase in costs or a decrease in revenues between 3% and 5%. CMS has estimated the burdens of this Interim Final Rule as cost per employee and maintains that the estimated burdens do not result in a "significant effect" that would require CMS to grant relief for small entities.

As noted above, AAAHC does not agree that the estimated burdens of rule implementation do not result in a "significant effect" that would require CMS to grant relief for small entities. As previously discussed, AAAHC is concerned about the effect of continuously mandated guidance and changes to systemwide stakeholders on patient care, and we urge CMS to consider granting relief to the facilities and other stakeholders that are expected to make these changes, namely those in the states in which enforcement of the rule is not enjoined as well as to other stakeholders including accreditation organizations in which operations continue to experience COVID-19 impact.

Alternative Consideration 4: CMS welcomes comments on the possible extension of the vaccination deadline by one (1) month.

With consideration for the various additional burdens not addressed in the CMS IFR, AAAHC does not believe that a blanket vaccination requirement alone is the most appropriate COVID-19 mitigation strategy where a variety of health care system-wide procedures and compliance measures already exist. Since compliance is nonetheless required of the AOs, AAAHC urges CMS to consider that the process to update the AAAHC Standards is similar to the process required of CMS when proposing new regulations. AAAHC must push standards through rigorous committee review, often a public comment period, and finally Board of Directors approval. As stated in the December 28, 2021, AO QSO, CMS expects accreditation organizations to begin surveying for the newly proposed requirements within thirty (30) days. AAAHC respectfully requests that CMS reconsider this requirement and engage AOs in a discussion of the different internal operational requirements of the accreditation organizations and the feasibility of this timeline. Each AO is unique, and we recommend that CMS consider a fair implementation process that does not inadvertently benefit AOs with greater resources. At the very least, AAAHC respectfully requests at least six (6) months to plan and adjust our budget for compliance with this new rule.

Alternative Consideration 5: CMS welcomes comments related to the agency's decision to apply a minimal compliance burden regarding staff proof of compliance with the mandate, knowing this decision could lead to forged documents and false statements, which may require future reconsideration of the decision.

Please note the AAAHC response above regarding vaccine status validation.

As discussed, while AAAHC supports CMS in its concern for and oversight role in ensuring patient safety and quality care, AAAHC does not support the CMS-mandated vaccine requirements as described in the rule. We appreciate the opportunity to submit this comment. For any questions regarding this comment, please contact Noel Adachi at 847-853-6060.

Sincerely,

Noel M. Adachi, MBA
President & CEO

Edwin Slade, DMD, JD
Board Chair