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HHS Secretary Xavier Becerra
CMS Administrator Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-3415-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS-3415-IFC: Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule with Comment Period (IFC), published in Vol. 86 No. 212 (61555-61627) on November 5, 2021

*Submitted electronically via* http://www.regulations.gov

Dear HHS Secretary Becerra and CMS Administrator Brooks-LaSure:

UnityPoint Health appreciates this opportunity to provide comments on Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination IFC. UnityPoint Health is one of the nation's most integrated health care systems. Through more than 33,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities, and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics, and home health agencies provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

UnityPoint Health appreciates the time and effort of CMS in developing this IFC. We respectfully offer the following input on specific areas outlined below:

## GENERAL COMMENTS

*The IFC is proposing to establish COVID–19 vaccination requirements for all staff including Medicare and Medicaid certified providers and suppliers.*

**Comment**: UnityPoint Health understands the effectiveness of vaccines as well as the importance of other infection prevention measures, particularly as it relates to the COVID-19 virus and the safety of our health care workforce, patients, and communities. In August 2021, UnityPoint Health announced a COVID-19 vaccine requirement for team members, who had until November 1, 2021, to become compliant with the vaccine policy. Exemptions are provided in accordance with state and federal law. **Vaccinating team members is a safe and effective way to protect team members and patients and help reduce the spread**

**of COVID-19.** Having a vaccine compliant workforce aligns with our values of protecting the health and safety of our patients, team members, and communities. **Nearly 99% of UnityPoint Health employees are compliant with our vaccine policy.**

**Effective in 2022, this rule is too late, disruptive to current and effective provider practices, and diverts resources from direct patient care to manage an overly broad vaccination compliance process**. It is important to note that in response to the COVID-19 virus and prior to the availability of a vaccine, UnityPoint Health quickly established policies and procedures in the Spring of 2020 to create a safe environment not only for our workforce but our patients. These practices were implemented without specific guidance or mandates from CMS or HHS but in reliance upon infectious disease prevention principles and science. **Our timely action focused on an overall prevention methodology using a risk-based approach – screening/testing, masking, and social distancing/isolation.** While UnityPoint Health cannot single handedly eliminate the COVID-19 virus, UnityPoint Health greatly reduced the spread of COVID-19 within our sites of care. **At the end of November 2021, exposure rate for UnityPoint Health's employees was 11% for work-related exposures compared to 89% for community-related exposures.** It is within the constructs of these highly effective internal processes that this IFC mandates changes disregarding local risk-based analyses by providers/suppliers to reduce exposure risk.

**The IFC also sets troublesome precedence, and UnityPoint Health urges CMS to withdraw the IFC as proposed**.

- Medicare/Medicaid Conditions of Participation (CoPs): CMS has chosen to place the omnibus COVID-19 health care staff vaccination requirements within the Medicare CoPs (i.e. health and safety regulations Medicare providers must meet to participate in the Medicare program) for certain providers/suppliers. **Vaccination requirements have not typically implicated Medicare CoPs nor should they.** CMS is not the federal agency charged with oversight of infectious disease management and, while CMS is charged with standards of practice for patient care, staff vaccinations are not a standard of practice for patient care. Additionally, Medicare is intended to promote access to health care services, and Medicare providers and suppliers are evaluated as a whole for compliance with the CoPs to meet the definition of a Medicare provider/supplier. Placing COVID-19 staff vaccination requirements within a CoP for which a provider/supplier may lose Medicare eligibility seems harsh and misplaced.

- Virus-Specific Protocols: While the COVID-19 pandemic is a global emergency, it will certainly not be the last public health emergency our nation faces. **By adopting infection specific regulations for this particular virus, these actions set a precedent for future regulations that potentially burden both the agency as well as health care providers/suppliers** – ultimately limiting the ability for the health care workforce to deliver high value and impactful care by instituting operational barriers. As the world continues to learn more about the current pandemic, it is even more evident that, having a rule designed for one specific infectious disease and at one point of time, does not allow for the ebb and flow of a disease nor permit health care providers/suppliers to be as nimble as they should be.

  Likewise, we believe that this rule is flawed in its targeted focus on one particular infection control

measure (i.e. vaccination) over other preventive measures to address a mutating virus in a global pandemic. We agree that it is scientifically proven that vaccines have palpable benefits. We do not believe that current vaccines are a silver bullet to the exclusion of other preventative measures. Throughout the years, many infectious diseases have effectively been managed through standard, scientifically proven, infection prevention measures such as screening, masking, and isolation, and without mandating various vaccines. Most health care facilities currently have highly effective processes in place today, especially in the hospital setting. While we encourage eligible individuals to obtain COVID-19 vaccinations, we fear that a federal mandate misdirects resources towards a long-term goal of virus elimination at the expense of a more immediate goal of virus control.

- Overlap: **A stand-alone vaccine mandate for health care should not be added to the plethora of other regulatory requirements targeting this global pandemic**. Although the IFC is more limited in scope, it overlaps with the Occupational Safety and Health Administration (OSHA) emergency temporary standard (ETS)[1] as well as guidance already deployed by the CDC. Further complicating this process are existing individual state requirements that may or may not allow certain employers to comply with the same standards CMS has outlined for the health care setting. For instance, Iowa legislation expanded the vaccination exemption requirements and extended unemployment benefits for employees refusing to be vaccinated[2], while the Illinois Legislature revised the Health Care Right of Conscience Act to prevent individuals from using the Act to avoid COVID vaccination and testing requirements[3]. These ever-changing rules in response to a disease state that is mutating and practice standards that are evolving leave health care providers/suppliers across the nation in an unenviable position. Spikes in hospitalized patients and workforce shortages are forcing health care providers/suppliers to lean into already exhausted resources all while managing disparate and even contradictory recommendations from multiple federal and state agencies and administrations.

## STAFF SUBJECT TO COVID-19 VACCINATION REQUIREMENTS

*This IFC requires applicable providers and suppliers to develop and implement policies and procedures under which all staff are vaccinated for COVID–19.*

[1] https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard

[2] House File 902 - Under the bill, an employer that requires an employee to receive a COVID-19 vaccine must waive the vaccination requirement if the employee requests a waiver and submits either of the following items: (1) A statement that receiving the vaccine is injurious to the health and well-being of the employee, or an individual residing with the employee; or (2) A statement that receiving the vaccine would conflict with the tenets and practices of a religion of which the employee is an adherent or member. Furthermore, should an employee be terminated for refusing to be vaccinated (having not gone through the waiver process described above), that person would still be eligible to receive unemployment benefits.

[3] Senate Bill 1169 - "It is not a violation of this Act for any person or public official, or for any public or private association, agency, corporation, entity, institution, or employer, to take any measures or impose any requirements, including, but not limited to, any measures or requirements that involve provision of services by a physician or health care personnel, intended to prevent contraction or transmission of COVID-19 or any pathogens that result in COVID-19 or any of its subsequent iterations".

**Comment**: **UnityPoint Health supports guidance that enables health care providers/suppliers to establish reasonable safety and quality standards for their own employees**. In this case, UnityPoint Health has established a vaccine requirement for our team members notwithstanding federal and state requirements. These standards were put in place in reliance on science and clinical best practices.

**Our main concern with the IFC is its expansive definition of "staff", which includes in addition to its own facility employees, [independent] licensed practitioners, students, trainees, volunteers, and individuals who provide care or services for the provider/supplier that may or may not be employed**. The IFC requires virtually everyone who walks into a facility to meet the requirement of vaccination or religious/medical exemption and places the burden of compliance on providers/suppliers. As proposed, this rule requires providers/suppliers to implement and manage a process for vaccine verification for those who enter a facility, including how frequently they visit, what type of encounters/interactions they have, and any potential exposures. Furthermore, this rule requires providers/suppliers to manage medical and religious processes for individuals who are not directly employed by the provider/supplier and requires disclosure of personal information from non-employees that is inappropriate to acquire, have knowledge of, and securely store. Overall, the scope of "staff" is unreasonable and creates administrative burdens that are time-consuming and ill-suited for health care providers/suppliers to control. Health care providers/suppliers should have the discretion to determine the level of contact with patients and direct patient care staff that warrants extra precautions and mitigation efforts and what those measures should include. We strongly encourage that CMS eliminate the vaccine tracking and documentation requirements for individuals who are not employees of a health care provider/supplier.

**From a social perspective, we are concerned with the potential chilling effect of the IFC on the health care workforce generally as well as the ability to secure ancillary services**. UnityPoint Health agrees that vaccination should be included in any multi-pronged approach for reducing health system burden, safeguarding health care workers and the people they serve, and ending the COVID–19 pandemic. That said, health care providers/suppliers should be able to dictate the multi-pronged approach inclusive of other infection prevention measures (*i.e.,* masking, social distancing, etc.) and scope without a federal mandate. When the health care industry is singled out for further regulation with preference mandated for a particular tool, health care loses. Valued employees have been leaving the field, and future workers are deterred from pursuing these careers. In addition, providers/suppliers will experience hardships in securing contracted services under the IFC. Non-health care services, such as construction and maintenance (e.g. plumbers, electricians, construction workers, architects, etc.) are reluctant to work in a health care setting because of the IFC and other federal requirements. As a result of this overly broad rule, we are anticipating delays impacting our ability to routinely fix and maintain facilities to provide safe patient care.

## DETERMINING WHEN STAFF ARE CONSIDERED "FULLY VACCINATED"

*This IFC requires that providers and suppliers ensure that staff are fully vaccinated for COVID–19, which, for purposes of these requirements, is defined as being 2 weeks or more since completion of a primary vaccination series.*

**Comment**: As this rule targets one infectious disease that is mutating, **regulatory mandates should focus**

**on guardrails and not absolutes.** This is perhaps most evident in the attempt to define "fully vaccinated." It is worth reminding CMS that this pandemic reached the United States less than two years ago. The virus is far from being understood, and tools to combat it are still under development and refinement. At the time of this writing, the CDC revised for the sixth time its COVID-19 isolation and quarantine guidance for health care workers[4] and further guidance was offered for mitigating workforce shortages[5]. It would seem that the definition of "fully vaccinated" would be subject to similar revisions, particularly as it includes a two-week timeframe from completion of the primary vaccination series that are still under development and emergency use authorizations. In addition, the rule imposes implementation complexities given the tracking of multiple vaccinations (some requiring at least two doses) of varying effectiveness and with booster recommendations still unsettled.

## DOCUMENTATION OF STAFF VACCINATIONS

*This IFC requires providers and suppliers to appropriately document all staff COVID-19 vaccines.*

**Comment**: UnityPoint Health has more than 33,000 employees. For this group alone, this requirement to track and securely document is time consuming. It is also disappointing that the IFC lists examples of acceptable forms of proof of vaccination – CDC COVID–19 vaccination record card (or a legible photo of the card); documentation of vaccination from a health care provider or electronic health record; or state immunization information system record. This requires health care providers/suppliers to assure that these specific documents, and potentially others, are maintained outside a personnel file. The burden for UnityPoint to both comply with documentation requirements for its own employee, and also respond to the request from our patients to provide this same information for their own employers has created and additional administrative burden on our already challenged workforce. **Given the scope of "staff" to be monitored and documented, UnityPoint Health urges CMS to consider allowing health care providers/suppliers to utilize an attestation process to demonstrate vaccine compliance, especially as it relates to individuals outside the employ of the provider/supplier.**

## VACCINE EXEMPTIONS

*This IFC requires that providers and suppliers included in this IFC establish and implement a process by which staff may request an exemption from COVID–19 vaccination requirements based on an applicable Federal law.*

**Comment**: UnityPoint Health recognizes exemptions to our COVID-19 vaccine requirement for medical and religious reasons. **We support having an exemption process; however, divergent requirements from federal and state agencies has caused confusion and extra burden**. In general, we urge flexibility for health care providers/suppliers to operationalize exemptions following existing federal and state laws.

## CONTINGENCY PLANNING

*This IFC requires that providers and suppliers make contingency plans in consideration of staff that are not*

[4] CDC, Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2, Interim Guidance for Managing Healthcare Personnel with SARS-CoV-2 Infection or Exposure to SARS-CoV-2 | CDC
[5] CDC, Strategies to Mitigate Healthcare Personnel Staffing Shortages, https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html

*fully vaccinated to ensure that they will soon be vaccinated and will not provide care, treatment, or other services for the provider or its patients until such time as such staff have completed the primary vaccination series for COVID–19 and are considered fully vaccinated, or, at a minimum, have received a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine.*

**Comment**: **While contingency planning may already be included in most vaccine policies, the level of detail as a condition of participation within the IFC is burdensome and will likely require ongoing monitoring and revisions**.

## ENFORCEMENT

*CMS will issue interpretive guidelines, which include survey procedures, following publication of this IFC. These guidelines will advise and train State surveyors on how to assess compliance with the new requirements among providers and suppliers.*

**Comment**: As written, the IFC is open to disparate interpretation from both the agency and providers/suppliers. **On December 28, 2021, CMS issued the interpretive guidelines, which is another layer to decipher for compliance and varied interpretation that will be embedded in the survey process**. For health care providers/suppliers, this equates to additional time and effort to evaluate the rule, educate the workforce, vendors and contracted services, as well as deploy change management. Due to the timing of issuance, UnityPoint Health was not able to thoroughly review these guidelines and include formal comments within this letter. We anticipate that there will be questions and urge State surveyors to exercise leniency during initial onsite reviews.

## ADMINISTRATIVE BURDEN

*The IFC estimates costs for the development of associated policies and procedures as well as for the tracking and secure maintenance of required documentation.*

**Comment**: The IFC greatly underestimates costs to operationalize this mandate. As an integrated health system, UnityPoint Health includes ambulatory surgery centers, hospices, PACE organizations, hospitals, long-term care facilities, home health agencies, critical access hospitals, community mental health centers, and rural health clinics. We will focus our comments on hospitals as representative of our health care delivery footprint.

- Policies and Procedures: First, the IFC acknowledges that many hospitals have already developed policies and procedures requiring COVID-19 vaccinations for staff. This is true for our hospitals and we believe this to be true for most of our industry competitors. By layering on regulatory requirements to pre-existing policies, this is a step backwards for hospitals that have evaluated the situation, timely adopted policies, and acclimated these policies with staff and the communities. It has created questions and confusion when previously adopted policies required changes to comply with the IFC mandate. **We generally disfavor a regulatory approach to deploy universal and prescriptive measures for all hospitals**, when the measures are really targeted to a minority of stakeholders (i.e. hospitals lacking such policies). **A preferred approach would be to incentivize adoption of these policies, rather than to force adoption with potentially severe consequences related to violations of Medicare/Medicaid CoPs**.

  Second, we continued to be frustrated by the seeming lack of understanding by CMS of the time

and effort needed to operationalize rules, including this IFC. For each hospital, CMS estimates a total of 12 hours of effort – 8 hours by hospital infection preventionist, 2 hours by a director of nursing, and 2 hours by an administrator. To effectively manage a process of this magnitude, a hospital needs to interpret regulations, assess operational impact, develop processes, and then implement, maintain, securely store, and audit information to ensure compliance. **We respectfully suggest that this takes a village beyond the three positions listed by CMS and that a total of 1.5 days is a gross underestimate of the time needed to go live for vaccine policies and procedures.** In our experience, this has taken multiple (10-15) senior leaders from across the organization (Clinical Leaders, Infection Prevention, Human Resources, Health Information Technology, Legal, Compliance, Government and External Affairs, Supply Chain, Medical Staff Office Management and Marketing and Communications) to support this vaccine requirement. For our organization, this has required weekly meetings since the release of the IFC, with more effort early on to compare these requirements against our existing policies and procedures. With the release of the OSHA rule as well as updated CDC guidance documents, time and effort exponentially increased in order to untangle this regulatory web, and to respond to state and federal requirements have amended no less than six times our original COVID-19 vaccination policy.

Third, **we are concerned with the ongoing effort to maintain these policies and procedures**. The IFC assumes the work it takes to manage this regulation is static. The COVID-19 virus is anything but static. In 2021, the virus has mutated resulting in countless variants, clinical protocols and treatments have evolved, and federal guidance has consistently changed. Even if we were to accept the 12-hour time and effort estimate, we do believe that once adopted these policies will need to be frequently monitored and revised to reflect current science and clinical practice.

- Document storage: In terms of reviewing and documenting vaccination status, CMS has requested input for estimate improvement. We agree that various sites of care will likely have differing roles with capacity for documentation. That said, the IFC relies heavily on clinical or management positions for review. **For documentation outside an exemption process, this task can be accomplished by non-clinical staff, such as clerks or other administrative personnel. We are concerned that estimates for this function heavily rely upon registered nurses (RNs).** There is an overall nursing shortage in the United States, and as we struggle to fill our own nursing vacancies, we do not support estimates that have RNs performing these administrative tasks. The estimated 505,631 hours by RNs to support hospital COVID-19 vaccination documentation should be spent for direct patient care. For the exemption process, this review would likely involve human resource and/or compliance personnel.

  **We encourage CMS to revisit the number of individuals to be tracked**. During the pandemic, the health care workforce generally has been more transient, which equates to tracking vaccination status for individuals at multiple facilities by multiple providers/suppliers. The reality is that new employees are onboarded frequently. This is especially true in an era of traveling support staff and traveling nurses.

  Record maintenance and storage requirements also create administrative burdens that do not

appear to have been fully vetted. **The IFC indicates that providers/suppliers have the ability to use the appropriate tracking tools of their choice. While we appreciate the flexibility, we should note that this latitude does not excuse compliance with state and federal privacy requirements or alleviate cybersecurity concerns.** Both add to operational costs. The IFC makes reference to a CDC staff vaccination tracking tool[6], in this case a generic Excel-based tool. While Excel is a great tool for basic data management, we have concerns with basic spreadsheets being used to house staff personal health information (PHI). In an era of heighten cybersecurity, an Excel-based tool lacks the essential functions to securely store PHI level data and, as a tool tailored for manual entry, there is also a heightened potential for human error.

**The use of additional documentation tools, outside of an organization's patient and employee health EHRs, requires added technical support and appropriate storage on the back side**. With any new tool or database, it takes information technology support staff time and funds to license and deploy tools. Once data has been incorporated within these tools, it is the responsibility of the provider/supplier to not only store but secure the use of these tools and information. For example, UnityPoint Health securely stores this type of information in a cloud-base location. Since the data has PHI/PII level data, there are extra steps to ensure the data is secure and meets appropriate security requirements, including multi-factor authorization use and regular auditing. We do not believe that CMS has adequately accounted for these additional financial and labor costs associated for these types of storage and security measures.

We are pleased to provide input on this IFC and its impact on our health system, our patients and communities served. This rule places burden on health care providers/suppliers to operationalize standards already in place in many facilities today. **UnityPoint Health recommends CMS withdraw the IFC in its entirety and recognize effective measures in place today.** To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at (319) 361-2336 or cathy.simmons@unitypoint.org .

Sincerely,

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Improvement

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[6] https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html