Supporting Statement – Part A

Omnibus COVID-19 Health Care Staff Vaccination (IFC) (CMS-10801)

Background

The purpose of this package is to request the Office of Management and Budget (OMB) approval of the information collection requirements (ICRs) for the requirements for mandatory staff COVID-19 vaccinations for the 15 providers and suppliers covered in CMS-3415-IFC, *Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination* (IFC). All 15 of those providers and suppliers are required to meet these requirements in order to participate in the Medicare and Medicaid Programs. Those providers and suppliers are listed below with the Code of Federal Regulations (CFR) section that sets forth the new requirements:

- Ambulatory Surgical Centers (ASCs) (§ 416.51)
- Hospices (§ 418.60)
- Psychiatric residential treatment facilities (PRTFs) (§ 441.151)
- Programs of All-Inclusive Care for the Elderly (PACE) (§ 460.74)
- Hospitals (acute care hospitals, psychiatric hospitals, hospital swing beds, long term care hospitals, children's hospitals, transplant centers, cancer hospitals, and rehabilitation hospitals/inpatient rehabilitation facilities) (§ 482.42)
- Long Term Care (LTC) Facilities, including Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), generally referred to as nursing homes (§ 483.80)
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) (§ 483.430)
- Home Health Agencies (HHAs) (§ 484.70)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs) (§§ 485.58 and 485.70)
- Critical Access Hospitals (CAHs) (§ 485.640)
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services (§ 485.725)
- Community Mental Health Centers (CMHCs) (§ 485.904)
- Home Infusion Therapy (HIT) suppliers (§ 486.525)
- Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs) (§ 491.8)
- End-Stage Renal Disease (ESRD) Facilities (§ 494.30)

Currently, the United States (U.S.) is responding to a public health emergency (PHE) of respiratory disease caused by a novel coronavirus that has now been detected in more than 190 countries internationally, all 50 States, the District of Columbia, and all U.S. territories. The virus has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2), and the disease it causes has been named "coronavirus disease 2019" (COVID-19).

COVID-19 has had significant negative health effects—on individuals, communities, and the nation as a whole. Consequences for individuals who have COVID-19 include morbidity,

hospitalization, mortality, and post-COVID conditions (also known as long COVID). As of mid-October 2021, over 44 million COVID-19 cases, 3 million new COVID-19 related hospitalizations, and 720,000 COVID-19 deaths have been reported in the U.S.[1] Indeed, COVID-19 has overtaken the 1918 influenza pandemic as the deadliest disease in American history.[2]

Given recent estimates of undiagnosed infections and under-reported deaths, these figures likely underestimate the full impact.[3] In addition, these figures fail to capture the significant, detrimental effects of post-acute illness, including nervous system and neurocognitive disorders, cardiovascular disorders, gastrointestinal disorders, and signs and symptoms related to poor general well-being, including malaise, fatigue, musculoskeletal pain, and reduced quality of life. Recent estimates suggest more than half of COVID-19 survivors experienced post-acute sequelae of COVID-19 6 months after recovery.[4] The individual and public health ramifications of COVID-19 also extend beyond the direct effects of COVID-19 infections. Several studies have demonstrated significant mortality increases in 2020, beyond those attributable to COVID-19 deaths. In some percentage, this could be a problem of misattribution (for example, the cause of death was indicated as "heart disease" but in fact the true cause was undiagnosed COVID-19), but some proportion are also believed to reflect increases in other causes of death that are sensitive to decreased access to care and/or increased mental/emotional strain. One paper quantifies the net impact (direct and indirect effects) of the pandemic on the U.S. population during 2020 using three metrics: excess deaths, life expectancy, and total years of life lost. The findings indicate there were 375,235 excess deaths, with 83 percent attributable to direct, and 17 percent attributable to indirect effects of COVID-19. The decrease in life expectancy was 1.67 years, translating to a reversion of 14 years in historical life expectancy gains. Total years of life lost in 2020 was 7,362,555 across the U.S. (73 percent directly attributable, 27 percent indirectly attributable to COVID-19), with considerable heterogeneity at the individual State level.[5]

Because SARS-CoV-2, the virus that causes COVID-19 disease, is highly transmissible,[6] Centers for Disease Control and Prevention (CDC) has recommended, and CMS reiterated, that health care providers and suppliers implement robust infection prevention and control practices, including source control measures, physical distancing, universal use of personal protective equipment (PPE), SARS CoV-2 testing, environmental controls, and patient isolation or quarantine.[7,8,9,10] Available evidence suggests these infection prevention and control practices

1 https://covid.cdc.gov/covid-data-tracker/#datatracker-home.
2 https://www.statnews.com/2021/09/20/covid-19-set-to-overtake-1918-spanish-flu-as-deadliest-disease-in-american-history/.
3 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8354557/
4 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2784918
5 https://pubmed.ncbi.nlm.nih.gov/34469474/.
6 https://www.npr.org/sections/goatsandsoda/2021/08/11/1026190062/covid-delta-variant-transmission-cdc-chickenpox.
7 https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.
8 https://www.cms.gov/files/document/qso-21-08-nltc.pdf.
9https://www.cms.gov/files/document/qso-21-07-psych-hospital-prtf-icf-iid.pdf.
10 https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf.

have been highly effective when implemented correctly and consistently.[11,12]

Studies have also shown, however, that consistent adherence to recommended infection prevention and control practices can prove challenging—and those lapses can place patients in jeopardy.[13,14,15,16] A retrospective analysis from England found up to 1 in 6 SARS-CoV-2 infections among hospitalized patients with COVID-19 in England during the first 6 months of the pandemic could be attributed to healthcare-associated transmission.[17] In outbreaks reported from acute care settings in the U.S. following implementation of universal masking, unmasked exposures to other health care workers were frequently implicated.[18] A retrospective cohort study of health care staff behaviors, exposures, and cases between June and December 2020 in a large health system found more employees were exposed via coworkers than patients—and secondary cases among employees typically followed unmasked interactions with infected colleagues (for example, convening in breakrooms without proper source control).[19] The same study found that cases of health care worker infection associated with patient exposures could often be attributed to failure to adhere to PPE requirements (for example, eye protection). Past experience with influenza, and available evidence, suggest that vaccination of health care staff offers a critical layer of protection against healthcare-associated COVID-19 (HA-COVID-19). For example, evidence has shown that influenza vaccination of health care staff is associated with declines in nosocomial influenza in hospitalized patients,[20,21,22] and among nursing home

11 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2770287.
12 https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2777317.
13 https://www.pnas.org/content/pnas/118/1/e2015455118.full.pdf.
14 https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2782430.
15 https://www.medrxiv.org/content/10.1101/2021.09.08.21263057v1.
16 https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003816.
17 https://www.medrxiv.org/content/10.1101/2021.02.16.21251625v1.
18 https://jamanetwork.com/journals/jama/fullarticle/2773128.
19 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8349432/.
20 Weinstock DM, Eagan J, Malak SA, et al. Control of influenza A on a bone marrow transplant unit. *Infect Control Hosp Epidemiol*. 2000; 21:730-732.
21 Salgado CD, Giannetta ET, Hayden FG, Farr BM. Preventing nosocomial influenza by improving the vaccine acceptance rate of clinicians. *Infect Control Hosp Epidemiol* 2004; 25:923-928.
22 https://pubmed.ncbi.nlm.nih.gov/31384750/.

residents.[23,24,25,26,27,28,29] As a result, CDC, the Society for Healthcare Epidemiology of America, and others recommend—and a number of states require-- annual influenza vaccination for health care staff.[30,31,32]

In addition to preventing morbidity and mortality associated with COVID-19, currently approved or authorized vaccines also demonstrate effectiveness against asymptomatic SARS-CoV-2 infection. A recent study of health care workers in 8 states found that, between December 14, 2020 through August 14, 2021, full vaccination with COVID-19 vaccines was 80 percent effective in preventing RT-PCR–confirmed SARS-CoV-2 infection among frontline workers.[33] Emerging evidence also suggests that vaccinated people who become infected with the SARS-CoV-2 Delta variant have potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk.[34] For example, in a study of breakthrough infections among health care workers in the Netherlands, SARS-CoV-2 infectious virus shedding was lower among vaccinated individuals with breakthrough infections than among unvaccinated individuals with primary infections.[35]Fewer infected staff and lower transmissibility equates to fewer opportunities for transmission to patients, and emerging evidence indicates this is the case. The best data come from LTC facilities, as early implementation of national reporting requirements have resulted in a comprehensive, longitudinal, high quality data set. Data from CDC's National Healthcare Safety Network (NHSN) have shown that case rates among LTC facility residents are higher in facilities with lower vaccination coverage among staff; specifically, residents of LTC facilities in which vaccination coverage of staff is 75 percent or lower experience higher rates of preventable

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23 Hayward AC, Harling R, Wetten S, et al. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. *BMJ* 2006; 333: 1241-1246.

24 Potter J, Stott DJ, Roberts MA, et al. Influenza vaccination of healthcare workers in long-term-care hospitals reduces the mortality of elderly patients. J *Infect Dis*. 1997; 175:1-6.

25 Thomas RE, Jefferson TO, Demicheli V, et al. Influenza vaccination for health-care workers who work with elderly people in institutions: a systematic review. *Lancet Infect Dis*. 2006; 6:273-279.

26 Van den Dool C, Bonten MJM, Hak E, Heijne JCM, Wallinga J. The effects of influenza vaccination of health care workers in nursing homes: insights from a mathematical model. *PLoS Medicine.* 2008; 5:1453-1460.
Lemaitre M, Meret T, Rothan-Tondeur M, et al. Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial. *J Am Geriatr Soc*. 2009; 57:1580-1586.

27 Lemaitre M, Meret T, Rothan-Tondeur M, et al. Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial. *J Am Geriatr Soc*. 2009; 57:1580-1586.
Van den Dool C, Bonten MJM, Hak E, Heijne JCM, Wallinga J. The effects of influenza vaccination of health care workers in nursing homes: insights from a mathematical model. *PLoS Medicine.* 2008; 5:1453-1460.

28 Oshitani H, Saito R, Seiki N, et al. Influenza vaccination levels and influenza-like illness in long-term–care facilities for elderly people in Niigata, Japan, during an influenza A (H3N2) epidemic. *Infect Control Hosp Epidemiol*. 2000; 21:728-730.

29 https://pubmed.ncbi.nlm.nih.gov/31384750/.

30 https://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm.

31 https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/revised-shea-position-paper-influenza-vaccination-of-healthcare-personnel/E83D4D87FBBBD80C66A2A4926D00F4B8.

32 https://www.cdc.gov/phlp/publications/topic/vaccinationlaws.html.

33 https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm?s_cid=mm7034e4_w.

34 https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#ref43.

35 https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1.full.pdf.

COVID-19.[36] Several articles published in CDC's Morbidity and Mortality Weekly Reports (MMWRs) regarding nursing home outbreaks have also linked the spread of COVID-19 infection to unvaccinated health care workers and stressed that maintaining a high vaccination rate is important for reducing transmission.[37,38,39]

There is also some published evidence from other settings that suggest similar dynamics can be expected in other health care delivery settings. For example, a recent analysis from Yale New Haven Hospital (YNHH) found health care units with at least 1 inpatient case of HA-COVID-19 had lower staff vaccination rates.[40] Similarly, a small study in Israel demonstrated that transmission of COVID-19 was linked to unvaccinated persons. In 37 cases, patients for whom data were available regarding the source of infection, the suspected source was an unvaccinated person; in 21 patients (57 percent), this person was a household member; in 11 cases (30 percent), the suspected source was an unvaccinated fellow health care worker or patient.[41] While similarly comprehensive data are not available for all Medicare- and Medicaid-certified provider types, the available evidence for ongoing healthcare-associated COVID-19 transmission risk is sufficiently alarming in and of itself to compel CMS to take action.

A. Justification

1 . Need and Legal Basis

Need

In addition to healthcare-associated COVID-19 transmission risk discuss above under background, unvaccinated staff jeopardize patient access to recommended medical care and services, and these risks to patient health and safety warrant further CMS action. Fear of exposure to and infection with COVID-19 from unvaccinated health care staff can lead patients to themselves forgo seeking medically necessary care. In a small but informative qualitative study of 33 home health care

36 https://emergency.cdc.gov/han/2021/han00447.asp.

37 COVID-19 Outbreak Associated with a SARS-CoV-2 R.1 Lineage Variant in a Skilled Nursing Facility After Vaccination Program — Kentucky, March 2021." April 21, 2021. Available at https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e2.htm.

38 Postvaccination SARS-CoV-2 Infections Among Skilled Nursing Facility Residents and Staff Members — Chicago, Illinois, December 2020–March 2021." April 30, 2021. Available at https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e1.htm.

39 Effectiveness of the Pfizer-BioNTech COVID-19 Vaccine Among Residents of Two Skilled Nursing Facilities Experiencing COVID-19 Outbreaks — Connecticut, December 2020–February 2021." March 19, 2021. Available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7011e3.htm.

40 Roberts, S., Aniskiewicz, M., Choi, S., Pettker, C., & Martinello, R. (2021). Correlation of healthcare worker vaccination on inpatient healthcare-associated COVID-19. Infection Control & Hospital Epidemiology, 1-6. Doi:10.1017/ice.2021.414.

41 Moriah Bergwerk, M.B., B.S., Tal Gonen, B.A., Yaniv Lustig, Ph.D., Sharon Amit, M.D., Marc Lipsitch, Ph.D., Carmit Cohen, Ph.D., Michal Mandelboim, Ph.D., Einav Gal Levin, M.D., Carmit Rubin, N.D., Victoria Indenbaum, Ph.D., Ilana Tal, R.N., Ph.D., Malka Zavitan, R.N., M.A., et al. Covid-19 Breakthrough Infections in Vaccinated Health Care Workers. N Engl J Med 2021; 385:1474-1484. DOI: 10.1056/NEJMoa2109072. https://www.nejm.org/doi/full/10.1056/NEJMoa2109072

workers in New York City, one of the key themes to emerge from interviews with those workers was a keen recognition that "providing care to patients placed them in a unique position with respect to COVID-19 transmission. They worried…about transmitting the virus to [their clients]." They also noted that care for home bound clients might involve other health care staff, and they worried about "transmitting COVID-19…to one another."[42]

Anecdotal evidence suggests health care consumers have drawn similar conclusions—and this, too, has implications for overall health and welfare in health care settings. For example, CMS has received anecdotal reports suggesting individuals in care are refusing care from unvaccinated staff, limiting the extent to which providers and suppliers can effectively meet the health care needs of their patients and residents. Further, nationwide there are reports of individuals avoiding or forgoing health care due to fears of contracting COVID-19 from health care workers.[43,44,45] While avoidance of necessary care appears to have abated somewhat since the first months of the COVID-19 pandemic, it remains an area of concern for many individuals.[46,47]

Unvaccinated staff also present a threat to health care operations. Absenteeism due to COVID-19-related exposures or illness can create staffing shortages that disrupt patient access to recommended care. Data suggest the current surge in COVID-19 cases associated with emergence of the Delta variant has exacerbated health care staffing shortages. For example, 1 in 5 hospitals report that they are currently experiencing a critical staffing shortage.[48] Through the week ending September 19, 2021, approximately 23 percent of LTC facilities reported a shortage in nursing aides; 21 percent reported a shortage of nurses; and 10 to 12 percent reported shortages in other clinical and non-clinical staff categories.[49] And while some studies suggest overall staffing levels (as defined by nurse hours per resident day) have been relatively stable, this appears to be associated with concurrent decreases in patient demand (for example, resident census in nursing homes)—decreases that have ramifications for patient access to recommended and medically appropriate services.[50,51] Over half (58 percent) of LTC facilities participating in a recent survey conducted by the American Health Care Association and National Center for Assisted Living (AHCA/NCAL) indicated that they are limiting new admissions due to staffing shortages.[52]

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42 https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2769096).
43 J Anxiety Disord. 2020 Oct; 75: 102289. Published online 2020 Aug 19. Doi: 10.1016/j.janxdis.2020.102289
44 https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6936a4-H.pdf.
45 https://www.nahc.org/wp-content/uploads/2020/03/NATIONAL-SURVEY-SHOWS-HOME-HEALTH-CARE-ON-THE-FRONTLINES-OF-COVID-19-AND-CONTINUES-TO-BE-IN-A-FRAGILE-FINANCIAL-STATE.pdf.
46 https://www.urban.org/sites/default/files/publication/103651/delayed-and-forgone-health-care-for-nonelderly-adults-during-the-covid-19-pandemic_1.pdf.
47 Gale R, Eberlein S, Fuller G, Khalil C, Almario CV, Spiegel BM. Public Perspectives on Decisions About Emergency Care Seeking for Care Unrelated to COVID-19 During the COVID-19 Pandemic. JAMA Netw Open. 2021;4(8):e2120940. Doi:10.1001/jamanetworkopen.2021.20940.
48 Analysis of data submitted by hospitals through HHS Protect; accessed September 20, 2021.
49 Data reported through CDC's NHSN.
50 https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.02351.
51 https://www.npr.org/sections/health-shots/2021/10/14/1043414558/with-hospitals-crowded-from-covid-1-in-5-american-families-delays-health-care.
52 https://www.ahcancal.org/News-and-Communications/Fact-Sheets/FactSheets/Workforce-Survey-September2021.pdf.

Similarly, hospital administrators responding to an OIG pulse survey conducted during February 22–26, 2021, reported difficulty discharging COVID-19 patients to post-acute facilities (for example, nursing homes, rehabilitation hospitals, and hospice facilities) following the acute stage of the patient's illness. These delays in discharge affected available bed space throughout the hospital (for example, creating bottlenecks in ICUs and EDs) and delayed patient access to specialized post-acute care (such as rehabilitation).[53] The drivers of this staffing crisis are multi-factorial; however, illnesses and deaths associated with COVID-19 are exacerbating these staffing shortages across the health care system.

Vaccination is a powerful tool for protecting health and safety of patients, and, with the emergence and spread of the highly transmissible Delta variant, it has been an increasingly critical one to address the extraordinary strain the COVID-19 pandemic continues to place on the U.S. health system. While COVID-19 cases, hospitalizations, and deaths declined over the first 6 months of 2021, the emergence of the Delta variant reversed these trends.[54] Between late June 2021 and September 2021, daily cases of COVID-19 increased over 1200 percent; new hospital admissions, over 600 percent; and daily deaths, by nearly 800 percent.[55] Available data also continue to suggest that the majority of COVID-19 cases and hospitalizations are occurring among individuals who are not fully vaccinated. In a recent study of reported COVID-19 cases, hospitalizations, and deaths in 13 U.S. jurisdictions that routinely link case surveillance and immunization registry data, CDC found that unvaccinated individuals accounted for over 85 percent of all hospitalizations in the period between June and July 2021, when Delta became the predominant circulating variant.[56]

Unfortunately, health care staff vaccination rates remain too low in too many health care facilities and regions. For example, national COVID-19 vaccination rates for LTC facility, hospital, and ESRD facility staff are 67 percent, 64 percent, and 60 percent, respectively. Moreover, these averages obscure sizable regional differences. LTC facility staff vaccination rates range from lows of 56 percent to highs of over 90 percent, depending upon the State. Similar patterns hold for ESRD facility and hospital staff.[57,58,59] Given slow but steady increases in vaccination rates among staff working in these settings over time,[60] widespread availability of vaccines, and targeted efforts to facilitate vaccine access like the Federal Retail Pharmacy program,[61] vaccine

53 See HHS OIG reports OEI-09-21-00140 and OEI-06-20-00300, both accessed September 26, 2021.
54 https://emergency.cdc.gov/han/2021/han00447.asp.
55 Internal estimates based on data published at:
https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html; accessed September 24, 2021.
56 https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm?s_cid=mm7037e1_w.
57 LTC facility rates derived from data reported through CDC's NHSN and posted online at the Nursing Home COVID-19 Vaccination Data Dashboard: https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html; accessed September 15, 2021.
58 Dialysis facility rates derived from data reported through CDC's NHSN and posted online at the Dialysis COVID-19 Vaccination Data Dashboard: https://www.cdc.gov/nhsn/covid19/dial-vaccination-dashboard.html; accessed September 15, 2021.
59 Hospital data come from unpublished analyses of data reported to HHS and posted on HHS Protect.
60 Ibid. footnotes 62-64.
61 https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html.

hesitancy,[62] rather than other factors (for example, staff turnover) is likely to account for suboptimal staff vaccination rates.

While a significant number of health care staff have been infected with SARS-CoV-2,[63] evidence indicates their infection-induced immunity, also called "natural immunity," is not equivalent to receiving the COVID-19 vaccine. Available evidence indicates that COVID-19 vaccines offer better protection than infection-induced immunity alone and that vaccines, even after prior infection, help prevent reinfections.[64] Consequently, CDC recommends that all people be vaccinated, regardless of their history of symptomatic or asymptomatic SARS-CoV-2 infection.[65]

It is essential to reduce the transmission and spread of COVID-19, and vaccination is central to any multi-pronged approach for reducing health system burden, safeguarding health care workers and the people they serve, and ending the COVID-19 pandemic. Currently FDA-approved and FDA-authorized vaccines in use in the U.S. are both safe and highly effective at protecting vaccinated people against symptomatic and severe COVID-19.[66] Higher rates of vaccination, especially in health care settings, will contribute to a reduction in the transmission of SARS-CoV-2 and associated morbidity and mortality across providers and communities, contributing to maintaining and increasing the amount of healthy and productive health care staff, and reducing risks to patients, resident, clients, and PACE program participants.

Legal Basis

CMS has broad statutory authority to establish health and safety regulations, which includes authority to establish vaccination requirements. Section 1102 of the Act grants the Secretary of Health and Human Services authority to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is charged under the Act. Section 1871 of the Act grants the Secretary of Health and Human Services authority to prescribe regulations as may be necessary to carry out the administration of the Medicare program. Section 1863 of the Act provides that "[i]n carrying out his functions, relating to determination of conditions of participation by providers . . . the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies[.]" The statutory authorities to establish health and safety requirements for COVID-19 vaccination for each provider and supplier is listed in Table 1 below.

TABLE 1: Authorities for All Providers and Suppliers in CMS-3415-SECTION

Provider/Supplier	Statutory Authority

62 https://www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive.html..
63 https://covid.cdc.gov/covid-data-tracker/#health-care-personnel.
64 https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm?s_cid=mm7032e1_w.
65 https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination.
66 https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html Accessed 10/14/2021.

Ambulatory Surgical Centers (ASCs)	Sections 1102, 1832(a)(2)(f)(i), and 1833 (i)(1)(A), and 1871 of the Act
Hospices	Sections 1102,1861(dd), and 1871 of the Act
Psychiatric Residential Treatment Facilities (PRTFs)	Section 1102 and 1905(h)(1) of the Act
Programs of All-Inclusive Care for the Elderly (PACE)	Sections 1102, 1871, 1894, and 1934 of the Act
Hospitals	Sections 1102, 1861(e)(9), and 1871 of the Act
Long Term Care (LTC) Facilities	Sections 1102, 1819, 1871, and 1919 of the Act
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)	Sections 1102 and 1905(d)(1) of the Act
Home Health Agencies (HHAs)	Sections 1102, 1861(m), 1861(o), 1871, and 1891 of the Act
Comprehensive Outpatient Rehabilitation Facilities (CORFs)	Sections 1102, 1861(cc)(2)(J), and 1871 of the Act
Critical Access Hospitals (CAHs)	Sections 1102, 1820(e), and 1871 of the Act
Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (Organizations)	Sections 1102, 1861(p)(4), and 1871 of the Act
Community Mental Health Centers (CMHCs)	Sections 1102, 1861(ff)(3), 1832(a)(2)(J), 1866(e)(2), and 1871 of the Act
Home Infusion Therapy (HIT) Suppliers	Sections 1102, 1861(iii)(3)(D)(i)(IV), and 1871 of the Act
Rural Health Clinics (RHCs)/ Federally Qualified Health Centers (FQHCs)	Sections 1102, 1861(aa), 1871, and 1905(l)(2)(B) of the Act
End-Stage Renal Disease (ESRD) Facilities	Sections 1102, 1871, and 1881(b)(1)(A) of the Act

2. Information Users

The primary users of this information will be State agency surveyors, CMS, and the 15 providers and suppliers covered by this IFC for the purposes of ensuring compliance with Medicare and Medicaid requirements as well as ensuring the safety and quality of care provided by these providers and suppliers. The ICRs specified in the regulations may be used as a basis for determining whether a provider or supplier is meeting the COVID-19 staff vaccination requirements to participate in the Medicare program. The information will also be used by other health care organizations and policymakers, such as the Centers for Disease Control and Prevention (CDC) and state and local public health agencies, to inform future health care policy related to infectious diseases.

3. Use of Information Technology

The providers and suppliers covered by this IFC may use health information technologies (HIT) to store and manage records, consistent with statutory and regulatory requirements for record keeping and confidentiality. Use of certified HIT technology is encouraged but not required, as some facilities, particularly small or rural facilities, may not have electronic capacity at this time. Facilities are free to take advantage of any technology advances they find appropriate for their needs.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This information collection does affect small businesses. However, the requirements have been established so as to be sufficiently flexible for facilities to meet them in a way consistent with their existing operations. Providers and suppliers have the flexibility to establish their own policies and procedures to meet the new requirements.

6. Less Frequent Collection

CMS does not collect this information directly from facilities on a scheduled basis. Facilities are expected to collect and maintain their own records in a timely fashion and to be able to provide necessary records to State or Federal surveyors when needed to demonstrate compliance with the requirements for participation. With less frequent collection, CMS would not be able to assess or ensure compliance with the requirements.

7. Special Circumstances

There are no special circumstances for collecting this information.

8. Federal Register/Outside Consultation

The Federal Register notice of the Medicare and Medicaid Programs; Omnibus COVID–19 Health Care Staff Vaccination Interim final rule with comment period (CMS-3415-IFC) published on November 5, 2021 (86 FR 61555).

9. Payments/Gifts to Respondents

There are no payment or gifts to respondents.

10. Confidentiality

We do not pledge confidentiality of aggregate data. We pledge confidentiality of resident-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a).

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates (Hours & Wages)

For the estimated information collection requirements (ICRs) costs contained in the analysis below, we used data from the U.S. Bureau of Labor Statistics (BLS) to determine the mean hourly wage for the positions used in this analysis.[67] For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. The adjusted hourly wages for each position used in this analysis are indicated below in Table 2.

TABLE 2: Summary Information of Estimated Mean Hourly and Adjusted Hourly Wages

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
29-1228	Physicians, All Others; and Ophthalmologist, except Pediatric) (General Medical and Surgical Hospitals)	LTC Facility Medical Director	$85.70	$171
29-1141	Registered Nurses (Nursing Facilities/ Skilled Nursing Facilities)	LTC Facility Registered Nurse (RN): LTC Facility Infection Preventionist (IP); ICFs-IID RN	$34.66	$69
29-1141	Registered Nurses (Home Health Care Services)	HHA RN; RN HIT; ESRD RN	$36.48	$73
29-1141	Registered Nurses (General Medical and Surgical Hospitals)	RN Hospice; RN Hospital; RN CAH	$39.27	$79
29-1141	Registered Nurses (Psychiatric and Substance Abuse Hospitals)	RN PRTF	$37.14	$74

67 BLS. *May 2020 National Occupational Employment and Wage Estimates United* States. United States Department of Labor. Accessed at https://www.bls.gov/oes/current/oes_nat.htm. Accessed on August 25, 2021.

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
11-9111	Medical and Health Services Managers (Nursing Facilities/Skilled Nursing Facilities)	LTC Facility Director of Nursing (DON); ICFs-IID Administrator	$48.15	$96
11-9111	Medical and Health Services Managers (General Medical and Surgical Hospitals)	Hospice Administrator; Hospital Administrator; Hospital DON; CAH DON; CAH Administrator; PRTF Administrator	$61.22	$122
11-9111	Medical and Health Services Managers (Home Health Care Services)	HHA Administrator; HIT Administrator; ESRD Administrator	$48.50	$97
29-1215	Family Medicine Physicians (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Physician and Medical Director	$105.75	$212
29-1071	Physician Assistants (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Physician Assistant	$55.34	$111
29-1171	Nurse Practitioners (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Nurse Practitioner	$53.51	$107
29-1123	Physical Therapists (Ambulatory Health Care Services, Offices of Other Health Practitioners)	Physical Therapist	$41.91	$84
29-1141	Registered Nurses (national mean hourly wage)	Ambulatory Surgery Center (ASC) Infection Control Professional (ICP)	$38.47	$77
11-9111	Medical and Health Services Managers (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Administrator	$54.18	$108

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
11-9111	Medical and Health Services Managers (Ambulatory Health Care Services, Outpatient Care Centers)	Community Mental Health Center (CHMC) Administrator	$56.34	$113
11-9111	Medical and Health Services Managers (Ambulatory Health Care Services, Other Ambulatory Health Care Services)	Ambulatory Surgery Center (ASC) Administrator, Organization Administrator, and Comprehensive Outpatient Rehabilitation Facility (CORF) Administrator	$49.03	$98
29-9092	General Counselors (Ambulatory Health Care Services, Outpatient Care Centers)	Community Mental Health Center (CHMC) Mental Health Counselor	$59.17	$118

In this analysis, we used specific resources to estimate the burden for the providers and suppliers in this rule. Based upon our experience, there are minimal fluctuations in the numbers of providers and suppliers monthly. Thus, unless otherwise indicated, all of the numbers for the providers and suppliers in this analysis were located on September 1, 2021 on the Quality, Certification & Oversight Reports (QCOR) website at https://qcor.cms.gov/main.jsp.

This analysis is also based upon certain assumptions. We believe that many of the providers and suppliers covered in this rule have already either encouraged their employees to get vaccinated for COVID-19 or have mandates for the vaccine. Mandates for employees to be vaccinated for COVID-19 can result from State, county, or local actions or result from a decision by the facility. These facilities would likely have already developed policies and procedures, as well as documentation requirements, related to their employees being vaccinated for COVID-19. However, we have no reliable method to estimate the number or percentage of these facilities. In addition, it is likely that those facilities would not comply with all of the requirements in this rule. For example, many facilities might not define "employees" as set forth in this rule. Each facility would have to review its policies, procedures, and documentation requirements to ensure that they comply with the requirements in this rule. Hence, based upon these assumptions, this analysis will assess the burden for all facilities and employees for each provider and supplier type.

We also made some assumption regarding analysis of the burden for the documentation requirements. If an employee receives the appropriate vaccinations, reviewing and documenting that the employee has been vaccinated would likely only require 1 to 3 minutes, depending upon how the facility is documenting the vaccination, which is likely to vary substantially between facilities. However, for employees that request exemptions or have to be contacted repeatedly for the appropriate documentation, it would likely take more time to comply with this requirement. At a minimum, both the initial request for the exemption and the final determination would have to be documented. In cases where the exemption was denied and the employee receives the appropriate vaccinations, those vaccine doses would also have to be documented. There might also be additional documentation that would need to be copied or scanned for their records. While the documentation for employees requesting an exemption would require more burden, we believe that there would only be a small percentage of employees that would request an exemption. Since we have no reliable method for estimating a number or percentage of employees who would be in each category, we will analyze the burden for the documentation requirements using 5 minutes or 0.0833 hours for each employee.

The position of the individual who would perform the activities related to the documentation requirement would also vary depending upon the type of provider or supplier and whether the employee requested an exemption. If the employee has been vaccinated in compliance with this rule, an administrative support person might review their vaccination card and document that the employee has been vaccinated. However, if an administrative support person performs these activities, we believe an administrator or another member of the health care staff would be responsible for overseeing these activities. For other providers and suppliers, a nurse would likely be assigned to verify and document vaccination status. If an employee requests an exemption, we believe that a nurse, another health care professional, or an administrator would likely review the request and document it. Some other providers or suppliers might have an administrator or another member of the health care staff perform these activities. Thus, for this analysis, if a provider is required to have at least one infection preventionist (IP), such as hospitals, we believe the IP would be responsible for documenting the vaccination status for all employees. For other providers and suppliers, we assessed the burden using a registered nurse (RN), another member of the health care staff, such as a physical therapist, or an administrator.

The estimates for the ICRs that follow are largely based on our experience with these various providers. However, given the uncertainty and rapidly changing nature of the current pandemic, we acknowledge that there will likely need to be revisions to these requirements over time.

A. Ambulatory Surgical Centers (ASCs) - § 416.51(c), "COVID-19 Vaccination of Staff"

1. Policies and procedures

At § 416.51(c), we require ASCs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and track and maintain documentation of their vaccination status. Each ASC must also have a contingency plan for any staff that are not fully vaccinated according to this rule.

The ICRs for this section would require each ASC to develop the policies and procedures needed to satisfy all of the requirements in this section. Based upon our experience with ASCs, we believe some centers have already developed policies and procedures requiring COVID-19 vaccination for staff. However, each ASC will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this section, especially that their policies and procedures cover all of the center staff as identified in the section. Hence, we will base our estimate for this ICR on all 6,071 ASCs. We believe activities associated with this SECTION would be performed by the RN functioning as the designated and qualified infection control professional (ICP) and ASC administrator as analyzed below.

The ICP would conduct research and then either modify or develop the policies and procedures needed to comply with this section's requirements. The ICP would work with the ASC administrator in developing these policies and procedures. For the ICP, we estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 2, the ICP's total hourly cost is $77. Thus, for each ASC, the burden for the ICP would be 8 hours at a cost of $616 (8 hours x $77). For the ICPs in all 6,071 ASCs, the burden would be 48,568 hours (8 hours x 6,071 ASCs) at an estimated cost of $3,739,736 ($616 x 6,071 ASCs).

As discussed above, the revision and approval of these initial policies and procedures would also require activities by the ASC administrator. The administrator would need to have meetings with the ICP to discuss the revisions and approve the final policies and procedures. We estimate this would require 2 hours for the administrator. According to Table 2, the total hourly cost for the administrator is $98. The burden for the administrator in each ASC would be 2 hours at an estimated cost of $196 (2 hours x $98). For the administrators in all 6,071 ASCs, the burden would be 12,142 hours (2 hours x 6,071 ASCs) at an estimated cost of $1,189,916 ($196 x 6,071 ASCs).

Therefore, for all 6,071 ASCs, the estimated burden associated with the requirement for policies and procedures would be 67,010 hours (48,568 + 12,142) at a cost of $4,929,652 ($3,739,736 + $1,189,916.

2. Tracking, Documentation, and Storage

Section 416.51(c) also requires ASCs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the center's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $77 for each employee. According to Table 2, ASCs have 200,000 employees. Hence, the burden for these documentation requirements for all 6,071 ASCs would be 16,660 (0.0833 hours x 200,000 employees) hours at an estimated cost of $1,282,820 (16,660 hours x $77).

The total burden for all 6,071 ASCs for this requirement would be 83,670 (67,010 + 16,660) hours at an estimated cost of $6,212,472 ($4,929,652 + $1,282,820).

Following the approval of this package, the estimated burden for ASCs will henceforth be submitted to OMB under OMB control number 0938-0266 (expiration date July 31, 2024).

B. Hospices - § 418.60(d), "COVID-19 Vaccination of Facility Staff"

1. Policies and procedures

At § 418.60(d), we require hospices to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The hospice must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each hospice to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations are set forth at § 418.60 Condition of participation: Infection control, and require each hospice to maintain and document an infection control program to prevent and control infections and communicable diseases. The hospice must also follow accepted standards of practice, including the use of standard precautions to prevent the transmission of infections and communicable diseases. Thus, all hospices should already have infection prevention and control policies and procedures, but they likely do not comply with all of the requirements in this section.

All hospices would need to review their current policies and procedures and modify them to comply with all of the requirements in § 418.60(d) as set forth in this section. While we believe that many hospices have already addressed COVID-19 vaccination with their staff, we have no reliable means to estimate that number. Therefore, we will assess the burden for these requirements for all 5,556 hospices. We believe these activities would be performed by the RN and an administrator. According to Table 2, an RN in these settings has a total hourly cost of $79. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each hospice, the burden for the RN would be 8 hours at a cost of $632 (8 hours x $79). For all 5,556 hospices, the burden would be 44,448 hours (8 hours x 5,556 hospices) at an estimated cost of $3,511,392 ($632 x 5,556 hospices).

The revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 2, the total hourly cost for the administrator in this setting is $122. Hence, for each hospice, the burden would be 2 hours at an estimated cost of $244 (2 hours x $122). For all 5,556 hospices, the total burden would be 11,112 hours (2 hours x 5,556 hospices) at an estimated cost of $1,355,664 (5,556 hospices x $244).

Thus, the total burden for hospices to comply with the requirements for policies and procedures in this section is 55,560 hours (44,448 + 11,112) at an estimated cost of $4,867,056 ($3,511,392 + $1,355,664).

2. Tracking, Documentation, and Storage

Section 418.60(d) also requires hospices to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the hospice's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $79 for each employee. According to Table 2, hospices have 340,000 employees. Hence, the burden for these documentation requirements for all 5,556 hospices would be 28,322 (0.0833 hours x 340,000 employees) hours at an estimated cost of $2,237,438 (28,322 x 79).

Therefore, the total burden for all 5,556 hospices for this rule would be 83,882 (55,560 +28,322) hours at an estimated cost of $7,104,494 (4,867,056 + 2,237,438).

Following the approval of this package, these requirements and burden for hospices will henceforth be submitted to OMB under OMB control number 0938-1067 (expiration date March 31, 2024).

C. Psychiatric Residential Treatment Facilities (PRTFs) - § 441.151(c), "COVID-19 Vaccination of Facility Staff"

1. Policies and procedures

Section 441.151(c) requires PRTFs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The PRTF must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each PRTF to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations for PRTFs do not address infection prevention and control or vaccinations. Hence, although we believe that at least some PRTFs have already addressed COVID-19 vaccination of their staff, we will assess the burden for all 357 PRTFs.

We believe these activities would be performed by an RN and an administrator. According to Table 2, an RN's total hourly cost is $74. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each PRTF, the burden for the RN would be 8 hours at a cost of $592 (8 hours x $74). For all 357

PRTFs, the burden would be 2,856 hours (8 hours x 357 PRTFs) at an estimated cost of $211,344 ($592 x 357 PRTFs).

The revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 2, the total hourly cost for the administrator is $122. Hence, for each PRTF, the burden would be 2 hours at an estimated cost of $244 (2 x 122). For all 357 PRTFs, the total burden would be 714 hours (2 hours x 357 PRTFs) at an estimated cost of $87,108 (357 PRTFs x $244).

Thus, the total burden for all 357 PRTFs to comply with the policies and procedures requirements in this section for policies and procedures is 3,570 hours (2,856 + 714) at an estimated cost of $298,452 (211,344 + 87,108).

2. Tracking, Documentation, and Storage

Section 441.151(c) also requires PRTFs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require a RN 5 minutes or 0.0833 hours to perform the required documentation at an adjusted hourly wage of $74 for each employee. According to Table 2, PRTFs have 30,000 employees. Hence, the burden for these documentation requirements for all 357 PRTFs would be 2,499 (0.0833 hours x 30,000 employees) hours at an estimated cost of $184,926 (2,499 x 74).

Therefore, the total burden for all 357 PRTFs for this rule would be 6,069 (3,570 + 2,499) hours at an estimated cost of $483,378 (298,452 + 184,926).

Following the approval of this package, these requirements and burden for PRTFs will henceforth be submitted to OMB under OMB control number 0938-0833 (expiration date May 31, 2022).

D. Programs for All-inclusive Care for the Elderly (PACE) Organizations - § 460.74(d), "COVID-19 Vaccination of PACE Organization Staff"

1. Policies and procedures

Section 460.74(d) requires that PACE organizations to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. Each PACE organization must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each PACE organization to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 460.74 already require that each PACE organization follow accepted policies and standard

procedures with respect to infection control in place. Thus, all PACE organizations should have policies and procedures regarding infection prevention and control. We also believe that many have already addressed COVID-19 vaccination policies for their staff. However, since we do not have a reliable method to estimate how many have, we will assess the burden for all 141 PACE organizations.

All PACE organizations would need to review their current infection prevention and control policies and procedures and develop or modify them to satisfy the requirements in this section. We believe these activities would require an RN and an administrator. According to Table 2, an RN's total hourly cost is $74. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each PACE organization, the burden for the RN would be 8 hours at a cost of $592 (8 hours x $74). For all 141 PACE organizations, the burden would be 1,128 hours (8 hours x 141) at an estimated cost of $83,472 ($592 x 141 PACE organizations).

The revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 2, the total hourly cost for the administrator is $122. Hence, for each PACE organization, the burden would be 2 hours at an estimated cost of $244 (2 hours x $122). For all 141 PACE organizations, the total burden would be 282 hours (2 hours x 141 PACE organizations) at an estimated cost of $34,404 (141 PACE organizations x $244).

Thus, the total burden for all 141 PACE organizations to comply with the requirements for the policies and procedures is 1,410 hours (1,128 + 282) at an estimated cost of $117,876 (83,472 + 34,404).

2. Tracking, Documentation, and Storage

Section 460.74(d) also requires PACE organizations to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the PACE organization's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $74 for each employee. According to Table 2, PACE organizations have 10,000 employees. Hence, the burden for these documentation requirements for all 141 PACE organizations would be 833 (0.0833 hours x 10,000 employees) hours at an estimated cost of $61,642 (833 hours x $74).

Therefore, the total burden for all 141 PACE organizations for this rule would be 2,243 (1,410 + 833) hours at an estimated cost of $179,518 (117,876 + 61,642).

Following the approval of this package, the requirements and burden for PACE organizations will henceforth be submitted to OMB under OMB control number 0938-1326 (expiration date April 20, 2023).

E. Hospitals - § 482.42(g), "COVID-19 Vaccination of Hospital Staff"

1. Policies and procedures

At § 482.42(g), we require hospitals to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The hospital must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each hospital to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs already require hospitals to have an infection prevention and control program (IPCP) and an infection preventionist (IP). The IPCP must have methods to prevent and control the transmission of infection within the hospital and between the hospital and other settings. Thus, all 5,194 hospitals should already have infection prevention and control policies and procedures. However, each hospital would need to review their current policies and procedures and modify them, if necessary, to ensure compliance with all of the requirements in this section, especially that their policies and procedures cover all of the eligible facility staff identified in this section. Based upon our experience with hospitals, we believe many hospitals have already developed policies and procedures requiring COVID-19 vaccination for staff. Since we have no reliable means to estimate the number of hospitals that may have already addressed COVID-19 vaccination of their staff, we will base our estimate for these requirements on all 5,194 hospitals.

We believe these activities would be performed by the IP, the director of nursing (DON), and an administrator. The IP would need to research COVID-19 vaccines, modify the policies and procedures, as necessary, and work with the DON and administrator to develop the policies and procedures and obtain appropriate approval. For the IP, we estimate these activities would require 8 hours. According to Table 2, the IP's total hourly cost is $79. Thus, for each hospital, the burden for the IP would be 8 hours at a cost of $632 (8 hours x $79). For the IPs in all 5,194 hospitals, the burden would be 41,552 hours (8 hours x 5,194 hospitals) at an estimated cost of $3,282,608 ($632 x 5,194 hospitals).

The revision and approval of these policies and procedures would also require activities by the DON and an administrator. We believe these activities would require 2 hours each for the DON and an administrator. According to Table 2, the total adjusted hourly wage for both the DON and an administrator is $122. Hence, for each hospital, the burden would be 4 hours (2 hours x 2 administrator-level employees) at an estimated cost of $488 (4 hours x $122). The total burden for all 5,194 hospitals would be 20,776 hours (4 hours x 5,194 hospitals) at an estimated cost of $2,534,672 (5,194 hospitals x $488).

Therefore, for all 5,194 hospitals, the total burden for the requirements for policies and procedures is 62,328 hours (41,552 + 20,776) at an estimated cost of $5,817,280 (3,282,608 + 2,534,672).

2. Tracking, Documentation, and Storage

Section 482.42(g) also requires hospitals to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the hospital's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $79 for each employee. According to Table 2, hospitals have 6,070,000 employees. We could not locate a reliable number for critical access hospital (CAH) employees so they are included here with the hospital employees. Hence, the burden for these documentation requirements for all 5,194 hospital and 1,358 CAHs would be 505,631 (0.0833 hours x 6,070,000 employees) hours at an estimated cost of $39,944,849 (505,631 hours x $79).

Therefore, the total burden for this rule for all 5,194 hospitals and 1,358 CAHs (documentation burden only) would be 567,959 (62,328 + 505,631) hours at an estimated cost of $45,762,129 (5,817,280 + 39,944,849).

Following the approval of this package, these requirements and burden for hospitals will be submitted to OMB as part of an emergency reinstatement of an existing OMB control number 0938-0328 and henceforth included in that package.

F. Long-term Care (LTC) Facilities - § 483.80(i), "COVID-19 Vaccination of Facility Staff"

1. Policies and procedures

At § 483.80(i), we require LTC facilities to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The LTC facility must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each LTC facility to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 483.80(d)(1) and (2) already require LTC facilities to have policies and procedures to educate, offer, and document vaccination status for residents regarding the influenza and pneumococcal immunizations. In addition, § 483.80(d)(3) requires LTC facilities to educate, offer, and document the vaccination status for residents and staff for the COVID-19 immunizations. Based upon our experience with LTC facilities, we believe some facilities have already developed policies and procedures requiring COVID-19 vaccination for staff, including COVID-19 vaccine mandates. However, we have no reliable means to estimate the number or percentage of LTC facilities that have already mandated vaccination. Hence, we will base our estimate for this ICR on all 15,401 LTC facilities.

Each LTC facility would need to review its policies and procedures for § 483.80(d) and modify them to comply with the requirements in this rule at § 483.80(i) and obtain the appropriate review and approval. This would require conducting research and revising the policies and procedures as needed. We believe these activities would be performed by the infection preventionist (IP), director of nursing (DON), and medical director for the first year and the IP in subsequent years as analyzed below.

The IP would need to work with the DON and medical director to revise and finalize the policies and procedures. For the IP, we estimate this would require 2 hours initially to perform research and revise the policies and procedures to meet these requirements. According to Table 2, the IP's total hourly cost is $69. Thus, for each LTC facility, the burden for the IP would be 2 hours at a cost of $138 (2 hours x $69). For the IPs in all 15,401 LTC facilities, the burden would be 30,802 hours (2 hours x 15,401 facilities) at an estimated cost of $2,125,338 ($138 x 15,401 LTC facilities).

The revision and approval of these policies and procedures would also require activities by the DON and medical director. Both the DON and medical director would need to have meetings with the IP to discuss the revision, evaluation, and approval of the policies and procedures. We estimate this would require 1 hour for both the DON and medical director. According to Table 2, the total hourly cost for the DON is $96. The burden in the first year for the DON in each LTC facility would be 1 hour at an estimated cost of $96 (1 hour x $96). The burden would be 15,401 hours (1 hour x 15,401 LTC facilities) at an estimated cost of $1,478,496 ($96 x 15,401 LTC facilities) for all LTC facilities.

For the medical director, we have estimated the revision of policies and procedures would also require 1 hour. According to the chart above, the total hourly cost for the medical director is $171. For each LTC facility, this would require 1 hour for the medical director during the first year at an estimated cost of $171 (1 hour x $171). the burden for all LTC facilities would be 15,401 hours (1 hour x 15,401 LTC facilities) at an estimated cost of $2,633,571 ($171 x 15,401 LTC facilities).

Therefore, for all 15,401 LTC facilities in the first year, the estimated burden for the policies and procedures requirement would be 61,604 hours (30,802 + 15,401 + 15,401) at a cost of $6,237,405 (2,125,338 + 1,478,496 + 2,633,571).

2. Tracking, Documentation, and Storage

Section 483.80(i) also requires LTC facilities to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. The PRA package submitted under OMB Control No. 0938-1363 already provides for the documentation burden for the IP for the LTC facility's infection prevention and control program (IPCP) under which the requirements in this rule will also be located. We believe the burden for the documentation

requirements in this rule should be included in that burden. Therefore, we will not assess any additional burden for the documentation requirements in this rule.

Following the approval of this package, these requirements and burden for LTC facilities will henceforth be submitted to OMB under OMB control number 0938-1363 (expiration date June 30, 2022).

G. Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) - § 483.430(f), "COVID-19 Vaccination of Facility Staff"

1. Policies and procedures

At § 483.430(f), we require ICFs-IID to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The ICFs-IID must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each ICFs-IID to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 483.470(l) Standard: infection control requires that the ICFs-IID must provide a sanitary environment to avoid sources and transmission of infections. The facility must also implement successful corrective action in affected problem areas, maintain a record of incidents and corrective actions related to infections, and prohibit employees with symptoms or sign of a communicable disease from direct contact with clients and their food. Hence, ICFs-IID should already have policies and procedures for infection prevention and control.

We believe these activities would be performed by the RN. According to Table 2, an RN's total hourly cost is $69. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each ICFs-IID, the burden for the RN would be 8 hours at a cost of $552 (8 hours x $69). For all 5,780 ICFs-IID, the burden would be 46,240 hours (8 hours x 5,780 ICFs-IID) at an estimated cost of $3,190,560 ($552 x 5,780 ICFs-IID).

The revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 2, the total hourly cost for the administrator is $96. Hence, for each ICFs-IID, the burden would be 2 hours at an estimated cost of $192 (2 hours x $96). For all 5,780 ICFs-IID, the total burden would be 11,560 hours (2hours x 5,780 ICFs-IID) at an estimated cost of $1,109,760 (5,780 ICFs-IID x $192).

Thus, the total burden for all 5,780 ICFs-IID to comply with the requirements for policies and procedures is 57,800 hours (46,240 + 11,560) at an estimated cost of $4,300,320 (3,190,560 + 1,109,760).

2. Tracking, Documentation, and Storage

Section 483.430(f) also requires ICFs-IID to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $69 for each employee. According to Table 2, ICFs-IID have 80,000 employees. Hence, the burden for these documentation requirements for all 5,780 ICFs-IID would be 6,664 (0.0833 hours x 80,000 employees) hours at an estimated cost of $459,816 (6,664 hours x $69).

Therefore, the total burden for all 5,780 ICFs-IID for this rule would be 64,464 (57,800 + 6,664) hours at an estimated cost of $4,760,136 (4,300,320 + 459,816).

Following the approval of this package, the requirements and burden for ICFs-IID will henceforth be submitted to OMB under OMB control number 0938-1402 (expiration date September 30, 2024).

H. Home Health Services - § 484.70(d), "COVID-19 Vaccination of Home Health Agency Staff"

1. Policies and procedures

At § 483.70(d), we require home health agencies (HHAs) that provide home health services to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The HHA must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each HHA to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 483.70, Condition of participation: Infection prevention and control require each HHA to maintain and document an infection control program to prevent and control infections and communicable diseases. The HHA must follow accepted standards of practice, including the use of standard precautions to prevent the transmission of infections and communicable diseases. Thus, all HHA should already have infection prevent and control policies and procedures, but they likely do not comply with all of the requirements in this section.

All HHAs would need to review their current policies and procedures and modify them to comply with all of the requirements in § 483.70(d), as set forth in this SECTION. While we believe that many HHAs have already addressed COVID-19 vaccination with their staff, we have no reliable means to estimate that number. Therefore, we will assess the burden for these requirements for all 11,649 HHAs. We believe these activities would be performed by the RN and an administrator.

According to Table 2, an RN in home health services total hourly cost is $73. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each HHA, the burden for the RN would be 8 hours at a cost of $584 (8 hours x $73). For all 11,649 HHAs, the burden would be 93,192 hours (8 hours x 11,649 HHAs) at an estimated cost of $6,803,016 ($584 x 11,649 HHAs).

The revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 2, the total hourly cost for the administrator in home health services is $97. Hence, for each HHA, the burden would be 2 hours at an estimated cost of $194 (2 hours x $97). For all 11,649 HHAs, the total burden would be 23,298 hours (2 hours x 11,649 HHAs) at an estimated cost of $2,259,906 (11,649 HHAs x $194).

Thus, the total burden for all 11,649 HHAs to comply with the policies and procedures requirements for policies and procedures is 116,490 hours (93,192 + 23,298) at an estimated cost of $9,062,922 (6,803,016 + 2,259,906).

2. Tracking, Documentation, and Storage

Section 483.70(d) also requires HHAs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the agency's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $73 for each employee. According to Table 2, HHAs have 2,110,000 employees. Hence, the burden for these documentation requirements for all 11,649 HHAs would be 175,763 (0.0833 hours x 2,110,000 employees) hours at an estimated cost of $12,830,699 (175,763 hours x $73).

Therefore, the total burden for all 11,649 HHAs for this rule would be 292,253 (116,490 + 175,763) hours at an estimated cost of $21,893,621 (9,062,922 + 12,830,699).

Following the approval of this package, these requirements and burden for HHAs will henceforth be submitted to OMB under OMB control number 0938-1299 (expiration date June 30, 2024).

I. Comprehensive Outpatient Rehabilitation Facilities (CORFs) - § 485.70(n), "COVID-19 Vaccination of Facility Staff"

1. Policies and procedures

At § 485.70(n), we require CORFs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. Each CORF must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each CORF to develop the policies and procedures needed to satisfy all of the requirements in this section. This section requires CORF staff to receive the COVID-19 vaccine unless medically contraindicated as determined by a physician, advance practice registered nurse, or physician assistant acting within their respective scope of practice as defined by and in accordance with all applicable State and local laws. Based upon our experience with CORFs, we believe some facilities have already developed policies and procedures requiring COVID-19 vaccination for staff unless medically contraindicated. However, each CORF will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this section, especially that their policies and procedures cover all of the organization staff identified in this section. Hence, we will base our estimate for this ICR on all 159 CORFs. The CORF's governing body appoints an administrator who implements and enforces the facility's policies and procedures. Hence, we believe activities associated with this section would be performed by the administrator as analyzed below. The governing body would also need to review these policies and procedures, which would be included in its "legal responsibility for establishing and implementing policies regarding the management and operation of the facility."

The administrator would conduct research to either modify or develop policies and procedures. For the administrator, we estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 2, the administrator's total hourly cost is $98. Thus, for each CORF, the burden for the administrator would be 8 hours at a cost of $784 (8 hours x $98). For the administrators in all 159 CORFs, the burden would be 1,272 hours (8 hours x 159 CORFs) at an estimated cost of $124,656 ($784 x 159 CORFs).

The administrator would need to spend time attending governing body meetings to discuss and obtain approval for the policies and procedures; however, that would be a usual and customary business practice. Therefore, activities for the administrator associated with governing body approval for the policies and procedures are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

2. Tracking, Documentation, and Storage

Section 485.70(n) also requires CORFs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require an administrator 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $98 for each employee. According to Table 2, CORFs have 10,000 employees. Hence, the burden for these documentation requirements for all 159 CORFs would be 833 (0.0833 hours x 10,000 employees) hours at an estimated cost of $81,634 (833 hours x $98).

Therefore, the total burden for all 159 CORFs for this rule would be 2,105 (1,272 + 833) hours at an estimated cost of $206,290 (124,656 + 81,634).

Following the approval of this package, these requirements and burden for CORFs will henceforth be submitted to OMB under OMB control number 0938-1091 (expiration date November 30, 2022).

J. Critical Access Hospitals (CAHs) - § 485.640(f), "COVID-19 Vaccination of CAH Staff"

1. Policies and procedures

At § 485.640(f), we require CAHs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The CAH must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each CAH to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs already require CAHs to have an infection prevention and control program (IPCP) and an infection preventionist (IP). The IPCP must have methods to prevent and control the transmission of infection within the hospital and between the hospital and other settings. Thus, all 1,358 CAHs should already have infection prevention and control policies and procedures. However, each CAH would need to review their current policies and procedures and modify them, if necessary, to ensure compliance with all of the requirements in this section, especially that their policies and procedures cover all of the eligible facility staff identified in this section. Based upon our experience with CAHs, we believe many CAHs have already developed policies and procedures requiring COVID-19 vaccination for staff. Since we have no reliable means to estimate the number of CAHs that may have already addressed COVID-19 vaccination of their staff, we will base our estimate for these requirements on all 1,358 CAHs.

We believe these activities would be performed by the IP, the director of nursing (DON), and an administrator. The IP would need to research COVID-19 vaccines, modify the policies and procedures, as necessary, and work with the DON and administrator to develop the policies and procedures and obtain appropriate approval. For the IP, we estimate these activities would require 8 hours. According to Table 2, the IP's total hourly cost is $79. Thus, for each hospital, the burden for the IP would be 8 hours at a cost of $632 (8 hours x $79). For the IPs in all 1,358 CAHs, the burden would be 10,864 hours (8 hours x 1,358 CAHs) at an estimated cost of $858,256 ($632 x 1,358 CAHs).

The revision and approval of these policies and procedures would also require activities by the DON and an administrator. We believe these activities would require 2 hours each for the DON and an administrator. According to Table 2, the total adjusted hourly wage for both the DON and an administrator is $122. Hence, for each CAH the burden would be 4 hours (2 administrator-level employees x 2 hours) at an estimated cost of $488 (4 hours x $122). The total burden for all

1,358 CAHs would be 5,432 hours (4 hours x 1,358 CAHs) at an estimated cost of $662,704 (1,358 CAHs x $488).

Therefore, for all 1,358 CAHs the total burden for the requirements for policies and procedures is 16,296 hours (10,864 + 5,432) at an estimated cost of $1,520,960 ($858,256 + $662,704).

2. Tracking, Documentation, and Storage

Section 485.640(f) also requires CAHs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the CAH's policies and procedures for these activities is already accounted for above. Since we were unable to located a reliable number for CAH employees, the documentation burden for CAHs resulting from the documentation requirement in this rule is included in the hospitals' burden above.

Following the approval of this package, these requirements and burden for CAHs without DPUs will henceforth be submitted to OMB under OMB control number 0938-1043 (expiration date March 31, 2024). The requirements and burden for CAHs with DPUs will henceforth be submitted to OMB under OMB control number 0938-0328 which will need to be reinstated.

K. Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (Organizations) - § 485.725(f), "COVID-19 Vaccination of Organization Staff"

1. Policies and procedures

At § 485.725(f), we require organizations to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and the appropriate documentation is tracked and maintained. The organization must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each organization to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 485.725(a) require organizations to establish an infection-control committee of representative professional staff with overall responsibility for infection control. This committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure compliance with those policies and procedures. Based upon these requirements and our experience with organizations, we believe some organizations have already developed policies and procedures requiring COVID-19 vaccination for staff unless medically contraindicated. However, since we have no reliable means to estimate how many organizations have done this, we will assess the burden for all 2,078 organizations. All organizations would need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this section.

The types of therapists at each organization vary depending upon the services offered. For the

purposes of determining the COI burden, we will assume that the therapist is a physical therapist. We believe activities associated with this requirement would be performed by a physical therapist and administrator. A physical therapist would need to conduct research on the COVID-19 vaccines and then develop or modify policies and procedures that comply with the requirements in this section. The physical therapist would need to work with an administrator to make the necessary revisions. For the physical therapist, we estimate this would require 8 hours to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 2, the physical therapist's total hourly cost is $84. Thus, for each organization, the burden for the physical therapist would be 8 hours at a cost of $672 (8 hours x $84). For the physical therapists in all 2,078 organizations, the burden would be 16,624 hours (8 hours x 2,078 organizations) at an estimated cost of $1,396,416 ($672 x 2,078 organizations).

The revision and approval of these policies and procedures would also require activities by the administrator. The administrator would need to have meetings with the physical therapist to discuss the revisions and draft any necessary policies and procedures, as well as approve the final policies and procedures. We estimate this would require 2 hours for the administrator. According to Table 2, the total hourly cost for the administrator is $98. The burden for the administrator in each organization would be 2 hours at an estimated cost of $196 (2 hours x $98). For the administrators in all 2,078 organizations, the burden would be 4,156 hours (2 hours x 2,078 organizations) at an estimated cost of $407,288 (4,156 hours x $98).

Therefore, for all 2,078 organizations, the total burden for the requirements for policies and procedures is 20,780 hours (16,624 + 4,156) at an estimated cost of $1,803,704 (1,396,416 + 407,288).

2. Tracking, Documentation, and Storage

Section 485.725(f) also requires organizations to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the organization's policies and procedures for these activities is already accounted for above. We believe that this would require a physical therapist 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $84 for each employee. According to Table 2, these organizations have 10,000 employees. Hence, the burden for these documentation requirements for all 2,078 organizations would be 833 (0.0833 hours x 10,000 employees) hours at an estimated cost of $69,972 (833 hours x $84).

Therefore, the total burden for all 2,078 organizations for this rule would be 21,613 (20,780 + 833) hours at an estimated cost of $1,873,676 (1,803,704 + 69,972).

Following approval of this package, these requirements and burden for the organizations will henceforth be submitted to OMB under OMB control number 0938-0273 (expiration date June 30, 2024).

L. Community Mental Health Centers (CMHCs) - § 485.904(c), "COVID-19 Vaccination of

Center Staff"

1. Policies and procedures

At § 485.904(c), we require CHMCs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. Each facility must maintain documentation of their staff's vaccination status. Also, each facility must have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each CHMC to develop the policies and procedures needed to satisfy all of the requirements in this section. Based upon our experience with CHMCs, we believe some centers have already developed policies and procedures requiring COVID-19 vaccination for staff unless medically contraindicated. However, since we do not have a reliable means to estimate how many CMHCs have done so, we will estimate the burden based on all 129 CHMCs.

Each CMHC will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this section. Based on these requirements and our experience with CHMCs, we believe these activities would be performed by the CHMC administrator and a mental health counselor. The administrator would conduct research regarding the COVID-19 vaccines and then either modify or develop the policies and procedures necessary to comply with the requirements in this section. The administrator would send any recommendations for changes or additional policies or procedures to the mental health counselor. The administrator and mental health clinician would need to make the necessary revisions and draft any necessary policies and procedures. For the administrator, we estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 2, the administrator's total hourly cost is $113. Thus, for each CMHC, the burden for the administrator would be 8 hours at a cost of $904 (8 hours x $113). The burden for the administrators in all 129 CMHCs would be 1,032 hours (8 hours x 129 CMHCs) at an estimated cost of $116,616 ($904 x 129 CMHCs).

As discussed above, the revision and approval of these initial policies and procedures would also require activities by the mental health counselor. The administrator would need to have meetings with the mental health counselor to discuss the revisions and draft any necessary policies and procedures. We estimate this would require 2 hours for the mental health counselor. According to Table 2, the total hourly cost for the mental health counselor is $118. The burden for the mental health counselor in each CMHC would be 2 hours at an estimated cost of $236 (2 hours x $118). For the mental health counselors in all 129 CMHCs, the burden would be 258 hours (2 hours x 129 CMHCs) at an estimated cost of $30,444 (129 CMHCs x $236).

Therefore, for all 129 CMHCs, the total burden for the requirements for policies and procedures is 1,290 hours (1,032 + 258) at an estimated cost of $147,060 (116,616 + 30,444).

2. Tracking, Documentation, and Storage

Section 485.904(c) also requires CMHCs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the center's policies and procedures for these activities is already accounted for above. We believe that this would require an administrator 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $113 for each employee. According to Table 2, CMHCs have 140,000 employees. Hence, the burden for these documentation requirements for all 129 CMHCs would be 11,662 (0.0833 hours x 140,000 employees) hours at an estimated cost of $1,317,806 (11,662 hours x $113).

Therefore, the total burden for all 129 CMHCs for this rule would be 12,952 (1,290 + 11,662) hours at an estimated cost of $1,464,866 (147,060 + 1,317,806).

Following the approval of this package, these requirements and burden will henceforth be submitted to OMB under OMB control number 0938-1245 (expiration date April 30, 2023).

M. Home Infusion Therapy - § 486.525(c), "COVID-19 Vaccination of Facility Staff"

1. Policies and procedures

Section 486.525(c) requires home infusion therapy (HIT) suppliers to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The HIT supplier must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each HIT supplier to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at §486.525 already require that HIT suppliers provide their services in accordance with nationally recognized standards of practice. Thus, we believe most HIT suppliers should already have infection prevention and control policies and procedures, including COVID-19 vaccination. However, we have no reliable means to estimate how many suppliers have done so. Thus, we will base our burden estimate on all 337 HIT suppliers.

All HIT suppliers would need to review their current policies and procedures and develop or modify them to comply with all of the requirements in §486.525(c) as set forth in this section. We believe these activities would be performed by the RN and an administrator working for the HIT supplier. According to Table 2, an RN working with for a HIT supplier would have a total hourly cost of $73. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each HIT supplier, the burden for the RN would be 8 hours at a cost of $584 (8 hours x $73). For all 337 HIT suppliers, the burden would be 2,696 hours (8 hours x 337 HIT suppliers) at an estimated cost of $24,601 (337 HIT suppliers x $73).

The development and/or revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 2, the total hourly cost for the administrator working for a HIT supplier is $97. Hence, for each HIT supplier, the burden would be 2 hours at an estimated cost of $194 (2 hours x $97). For all 337 HIT suppliers, the total burden for the administrator would be 674 hours (2 hours x 337 HIT suppliers) at an estimated cost of $65,378 (337 HIT suppliers x $194).

Therefore, for all 337 HIT suppliers, the total burden for the requirements for policies and procedures is 3,370 hours (2,696 + 674) at an estimated cost of $89,979 (24,601 + 65,378).

2. Tracking, Documentation and Storage

Section 486.525(c) also requires HIT suppliers to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the supplier's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $73 for each employee. According to Table 2, HIT suppliers have 20,000 employees. Hence, the burden for these documentation requirements for all 337 HIT suppliers would be 1,666 (0.0833 hours x 20,000 employees) hours at an estimated cost of $121,618 (1,666 hours x $73).

Therefore, the total burden for all 337 HIT suppliers for this rule would be 5,036 (3,370 + 1,666) hours at an estimated cost of $211,597 (89,979 + 121,618).

Following the approval of this package, these requirements and burden for HIT suppliers will henceforth be submitted to OMB under OMB control number 0938-1377 (expiration date March 31, 2024).

N. Rural Health Clinics and Federally Qualified Health Clinics - § 491.8(d), "COVID-19 Vaccination of Staff"

1. Policies and procedures

At § 491.8(d), we require RHCs/FQHCs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. Each RHC/FQHC must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each RHC/FQHC to develop the policies and procedures needed to satisfy all of the requirements in this section. This SECTION requires clinic or center staff to receive the COVID-19 vaccine unless medically contraindicated as determined by a

physician, advance practice registered nurse, or physician assistant acting within their respective scope of practice as defined by and in accordance with all applicable State and local laws. Based upon experience with RHCs/FQHCs, we believe some clinics or centers have already developed policies and procedures requiring COVID-19 vaccination for staff unless medically contraindicated. However, since we do not have a reliable means to estimate how many facilities have already done so, we will base the burden analysis for this estimate on all 15,317 RHC/FQHCs (4,933 RHCs and 10,384 FQHCs).

Each RHC/FQHC will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this SECTION, especially that their policies and procedures cover all of the clinic or center staff identified in this SECTION. Current regulations require a physician, nurse practitioner, and physician assistant to participate in the development, execution, and periodic review of the policies and procedures.[68] Moreover, the RHC/FQHC operates under the medical direction of a physician. Based on these requirements and our experience with RHCs/FQHCs, we believe activities associated with this SECTION would be performed by the RHC administrator, physician, nurse practitioner, physician assistant, and medical director as analyzed below.

The administrator would conduct research to either modify or develop policies and procedures. The administrator would send any recommendations for changes or additional policies or procedures to the physician, nurse practitioner, and physician assistant. The administrator, physician, nurse practitioner, and physician assistant would need to make the necessary revisions and draft any necessary policies and procedures. The administrator would need to work with the medical director to obtain approval for the policies and procedures to be implemented. For the administrator, we estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 2, the administrator's total hourly cost is $108. Thus, for each RHC/FQHC, the burden for the administrator would be 8 hours at a cost of $864 (8 hours x $108). For the administrators in all 15,317 RHCs/FQHCs, the burden would be 122,536 hours (8 hours x 15,317 RHCs/FQHCs) at an estimated cost of $13,233,888 ($864 x 15,317 RHCs/FQHCs).

The revision and approval of these initial policies and procedures would also require activities by the physician, nurse practitioner, physician assistant, and medical director. The administrator would need to have meetings with the physician, nurse practitioner, and physician assistant to discuss the revisions and draft any necessary policies and procedures. The administrator would also need to have meetings with the medical director to obtain approval for the policies and procedures. We estimate this would require 2 hours each for the physician, nurse practitioner, and physician assistant. For the medical director, we estimate 1 hour would be required to perform this function. According to Table 2, the total hourly cost for the physician is $212. The burden for the physician in each RHC/FQHC would be 2 hours at an estimated cost of $424 (2 hours x $212). For the physicians in all 15,317 RHCs/FQHCs, the burden would be 30,634 hours (2 hours x 15,317 RHCs/FQHCs) at an estimated cost of $6,494,408 ($424 x 15,317 RHCs/FQHCs). The hourly cost for the nurse practitioner is $107. The burden for the nurse practitioner in each

68 42 CFR 491.7.

RHC/FQHC would be 2 hours at an estimated cost of $214 (2 hours x $107). For the nurse practitioners in all 15,317 RHCs/FQHCs, the burden would be 30,634 hours (2 hours x 15,317 RHCs/FQHCs) at an estimated cost of $3,277,838 ($214 x 15,317 RHCs/FQHCs). The hourly cost for the physician assistant is $111. The burden for the physician assistant in each RHC/FQHC would be 2 hours at an estimated cost of $222 (2 hours x $111). For the physician assistants in all 15,317 RHCs/FQHCs, the burden would be 30,634 hours (2 hours x 15,317 RHCs/FQHCs) at an estimated cost of $3,400,374 (15,317 RHCs/FQHCs x $222). The hourly cost for the medical director is $212. The burden for the medical director in each RHC/FQHC would be 1 hour at an estimated cost of $212. For the medical directors in all 15,317 RHCs/FQHCs, the burden would be 15,317 hours (1 hour x 15,317 RHCs/FQHCs) at an estimated cost of $3,247,204 (15,317 RHCs/FQHCs x $212).

Therefore, for all 15,317 RHCs/FQHCs, the estimated burden associated with the policies and procedures requirement would be 229,755 hours (122,536 + 30,634 + 30,634 + 30,634 + 15,317) at a cost of $29,653,712 (13,233,888 + 6,494,408 + 3,277,838 + 3,400,374 + 3,247,204).

2. Tracking, Documentation, and Storage

Section 491.8(d) also requires RHCs/FQHCs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the clinic's or center's policies and procedures for these activities is already accounted for above. We believe that this would require an administrator 5 minutes or 0.0833 hours to perform the required documentation at an adjusted hourly wage of $108 for each employee. According to Table 2, RHCs have 40,000 employees and FQHCs have 110,000 employees for a total of 150,000 employees. Hence, the burden for these documentation requirements for all 15,317 RHCs and FQHCs would be 12,495 (0.0833 hours x 150,000 employees) hours at an estimated cost of $1,349,460 (12,495 hours x $108).

Therefore, the total burden for all 15,317 RHCs and FQHCs for this rule would be 242,250 (229,755 + 12,495) hours at an estimated cost of $31,003,172 (29,653,712 + 1,349,460).

Following approval of this package, these requirements and burden for RHCs and FQHCs will henceforth be submitted to OMB under OMB control number 0938-0334 (expiration date March 31, 2023).

O. End-Stage Renal Disease (ESRD) Facilities - § 494.30(b), "COVID-19 Vaccination of Facility Staff"

1. Policies and procedures

Section 494.30(b) requires the ESRD facilities to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The ESRD facility must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each ESRD facility to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 494.30 already require that ESRD facilities follow standard infection control precautions. Thus, all ESRD facilities should have infection prevention and control policies and procedures. We believe that many ESRD facilities have already addressed COVID-19 vaccination for their staff. However, we have no reliable means to estimate how many ESRD facilities have done so. Thus, we will base our burden estimate on all 7,893 ESRD facilities.

All ESRD facilities would need to review their current policies and procedures and develop or modify them to comply with all of the requirements in §494.30(b) as set forth in this section. We believe these activities would be performed by the RN and an administrator. According to Table 2, an RN working with for an ESRD facility would have a total hourly cost of $73. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each ESRD facility, the burden for the RN would be 8 hours at a cost of $584 (8 hours x $73). For all ESRD facilities, the burden would be 63,144 hours (8 hours x 7,893 ESRD facilities) at an estimated cost of $4,609,512 (7,893 ESRD facilities x $584).

The development and/or revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 2, the total hourly cost for the administrator at an ESRD facility is $97. Hence, for each ESRD, the burden for the administrator would be 2 hours at an estimated cost of $194 (2 hours x $97). For all ESRD facilities, the total burden would be 15,786 hours (2 hours x 7,893 ESRD facilities) at an estimated cost of $1,531,242 (7,893 ESRD facilities x $194). Thus, the total burden for all ESRD facilities for the policies and procedures requirement would be 78,930 hours (63,144 + 15,786) at an estimated cost of $6,140,754 ($4,609,512 + $1,531,242).

2. Tracking, Documentation, and Storage

Section 494.30(b) also requires ESRD facilities to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at an adjusted hourly wage of $73 for each employee. According to Table 2, ESRD facilities have 170,000 employees. Hence, the burden for these documentation requirements for all 7,893 ESRD facilities would be 14,161 (0.0833 hours x 170,000 employees) hours at an estimated cost of $1,033,753 (14,161 hours x $73).

Therefore, the total burden for all 7,893 ESRD facilities for this rule would be 93,091 (78,930 + 14,161) hours at an estimated cost of $ 7,174,507 (6,140,754 + 1,033,753).

Following approval of this package, the requirements and burden for ESRD facilities will henceforth be submitted to OMB under OMB control number 0938-0386 (expiration date March 31, 2024).

Based upon the above analysis, the total burden for all of these ICRs is 1,555,487 hours at an estimated cost of $136,088,221. These costs are detailed in Table 3 below.

TABLE 3: Summary of Information Collection Burdens

Regulation (§) - Provider or Supplier	OMB Control No.	No. of Respondents	No. of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Labor Costs ($)
416.51(c) - Ambulatory Surgical Centers (ASCs) – Policies and Procedures	0938-0266	6,071	6,071	11	67,010	4,929,652
416.51(c) - ASCs - Documentation	0938-0266	6,071	200,000	0.0833	16,660	1,282,820
418.60(d) Hospices – Policies and Procedures	0938-1067	5,556	5,556	10	55,560	4,867,056
418.60(d) Hospices – Documentation	0938-1067	5,556	340,000	0.0833	28,322	2,237,438
441.151(c) - Psychiatric Residential Treatment Facilities (PRTFs) – Policies and Procedures	0938-1384	357	357	10	3,570	298,452
441.151(c) – PRTFs - Documentation	0938-1384	357	30,000	0.0833	2,499	184,926
460.74(d) - Programs for All Inclusive Care for the Elderly (PACE) – Policies and Procedures	0938-1326	141	141	10	1,410	117,876
460.74(d) – PACE - Documentation	0938-1326	141	10,000	0.0833	833	61,642
482.42(g) – Hospitals – Policies and Procedures	0938-0328	5,194	5,194	12	62,328	5,817,280
482.42(g) – Hospitals - Documentation	0938-0328	5,194	6,070,000	0.0833	505,631*	39,944,849
483.80(i) - Long Term Care (LTC) – Facilities (SNFs and NFs) – Policies and Procedures **	0938-1363	15,401	15,401	4	61,604	6,237,405

Regulation (§) - Provider or Supplier	OMB Control No.	No. of Respondents	No. of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Labor Costs ($)
483.430(f) - Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IIDs) – Policies and Procedures	0938-1402	5,780	5,780	10	57,800	4,300,320
483.430(f) – ICFs-IID - Documentation	0938-1402	5,780	80,000	0.0833	6,664	459,816
484.70(d) - Home Health Agencies (HHAs) – Policies and Procedures	0938-1299	11,649	11,649	10	116,490	9,062,922
484.70(d) – HHAs - Documentation	0938-1299	11,649	2,110,000	0.0833	175,763	12,830,699
485.70(n) - Comprehensive Outpatient Rehabilitation Facilities (CORFs) – Policies and Procedures	0938-1091	159	156	8	1,272	124,656
485.70(n) – CORFs - Documentation	0938-1091	159	10,000	0.0833	833	81,634
485.58(d) - Critical Access Hospitals (CAHs) – Policies and Procedures	0938-1043 and 0938-0328	1,358	1,358-	12	16,296	1,520,960
485.725(f) – Organizations Policies and Procedures	0938-0273	2,078	2,078	10	20,780	1,803,704
485.725(f) – Organizations - Documentation	0938-0273	2,078	10,000	0.0833	833	69,972
485.704(c) - Community Mental Health Centers (CMHCs) – Policies and Procedures	0938-1245	129	129	10	1,290	147,060
485.704(c) – CMHCs - Documentation	0938-1245	129	140,000	0.0833	11,662	1,317,806
486.525(c) - Home Infusion Therapy (HIT)	0938-1377	337	337	10	3,370	89,979

Regulation (§) - Provider or Supplier	OMB Control No.	No. of Respondents	No. of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Labor Costs ($)
Suppliers – Policies and Procedures						
486.525(c) – HITs - Documentation	0938-1377	317	20,000	0.0833	1,666	121,618
491.8(d) - Rural Health Clinics (RHCs) and Federally Qualified Health Clinics (FQHCs) – Policies and Procedures	0938-0334	15,317	15,317	15	229,755	29,653,712
491.8(d) – RHCs and FQHCs - Documentation	0938-0334	15,317	150,000	0.0833	12,495	1,349,460
494.30(b) - End Stage Renal Disease (ESRD) Facilities – Policies and Procedures	0938-0386	7,893	7,893	10	78,930	6,140,754
494.30(b) ESRD Facilities - Documentation	0938-0386	7,893	170,000	0.0833	14,161	1,033,753
Totals					**1,555,487**	**$136,088,221**

*We were not able to locate a reliable number for CAH employees only. The number for hospital employees includes both hospital and CAH employees.
**Since the documentation burden for the IPCP is already accounted for in the current PRA package, OMB Control No. 0938-1363, a separate burden for this rule was not assessed.

13. Capital Costs

There are no capital/maintenance costs associated.

14. Cost to Federal Government

The Federal government will sustain a burden from implementing and enforcing the interim final rule with comment, specifically due to additional survey time. Surveyors will require approximately 2-3 hours per survey to review and evaluate facility records in order to ensure compliance with the new staff vaccination requirements. These additional costs are estimated at $11.4 million annually.

Table 4: Non-Nursing Home Survey Cost Totals

	Current Facilities	Policy Recertification	FY22 Recertification Survey Count	Add'l survey hours	T18 Additional Cost per Survey	T19 Additional Cost per	FY22 T18 Additional Cost @	FY22 T19 Additional Cost @

	*	level				Survey	Policy Recert level+	Policy Recert level+
Hospital	5,232	3 years	1,742	2	$326.70		$569,195	
CAH	1,359	3 years	453	2	$326.70		$147,847	
ASC	6,127	3 years	2,040	2	$326.70		$666,563	
ESRD	7,931	3 years	2,641	2	$326.70		$862,822	
HHA	11,698	3 years	3,895	2	$163.35	$166.37	$636,319	$648,083
Hospice	5,875	3 years	1,956	2	$326.70		$639,148	
ICF	5,785	Yearly	5,785	2		$220.16		$1,273,626
OPT	2,097	6 years	350	2	$326.70		$114,410	
CORF	162	6 years	27	2	$326.70		$8,839	
PRTF	370	5 years	74	2	$326.70		$24,176	
CMHC	130	6 years	22	2	$326.70		$7,093	
RHC	5,013	6 years	837	2	$326.70		$273,504	
HIT	349	NA	NA	2	$326.70			
						Totals	$3,949,915	$1,921,709

*FACILITY TOTALS 12/12/21

+Survey costs only, does not include complaints or revisits

Table 5: LTC Facility Survey Cost Totals

	Current Facilities**	Additional Hours/Survey	T18 Addtl Cost/Surv	Medicare	T19 Addtl Cost/Surv	Medicaid
SNF	630	3	$394.80	$248,724.00		
SNF/NF	14,336	3	$197.40	$2,829,926.40	$165.12	$2,367,160.32
NF	304	3			$330.24	$100,392.96
				$3,078,650.40		$2,467,553.28

** Facility totals on 10/1/21

In addition to the survey costs outlined in Tables 4 and 5, there will be minimal costs associated with CMS staff managing the requirements associated with this interim final rule. However, all CMS staff costs will be incurred in the course of normal duties.

15. Changes to Burden

This is a new information collection requirement.

16. Publication/Tabulation Dates

There are no plans to publish the information collected.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number. The expiration date will also be published on www.cms.gov at https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Spotlight

18. Certification Statement

We have not identified any exceptions.