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Attorneys for Defendants

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA, MISSOULA DIVISION

MONTANA MEDICAL ASSOCIATION, ET. AL.,

Plaintiffs,

and

MONTANA NURSES ASSOCIATION,

Plaintiff-Intervenors,

v.

AUSTIN KNUDSEN, ET AL.,

Defendants.

No. CV-21-108-M-DWM

DECLARATION OF BRENT MEAD

I, Brent Mead, make the following Declaration under penalty of perjury:

1. I am counsel for Defendants in the above action, am competent to testify as to the matters set forth herein, and make this Declaration based on my own personal knowledge and/or belief. I am generally familiar with the claims, materials, documents, and pleadings regarding this matter.

2. Attached as Exhibit 1 is a true and correct copy of the enrolled version of House Bill 702.

3. Attached as Exhibit 2 is a true and correct copy of the Governor's amendatory letter and amendments to House Bill 702.

4. Attached as Exhibit 3 is a true and correct copy of the House Bill 702's status sheet from the Montana Legislature website.

5. Attached as Exhibit 4 is a true and correct copy of the Centers for Disease Control's Morbidity and Mortality Weekly Report for April 22, 2022.

6. Attached as Exhibit 5 is a true and correct copy of the Federal Register, Vol. 86, No. 91, Thursday May 13, 2021.

7. Attached as Exhibit 6 is a true and correct copy of State's Expert Report of Dr. Jayanta Bhattacharya (corrected).

8. Attached as Exhibit 7 is a true and correct copy of State's Expert Report and CV of Dr. Ram Durisetti.

9. Attached as Exhibit 8 is a true and correct copy of Plaintiff's 4th Supplemental Responses to Defendant's First Requests.

10. Attached as Exhibit 9 is a true and correct copy of Plaintiff's Responses to Defendant's First Combined Discovery Requests.

11. Attached as Exhibit 10 is a true and correct copy of the August 12, 2022, Letter to Christian Corrigan from Justin Cole.

12. Attached as Exhibit 11 is a true and correct copy of the August 29, 2022, Vol. 71, No. 33 of the Centers for Disease Control guidance.

13. Attached as Exhibit 12 is a true and correct copy of the Montana Department of Labor & Industry Press Release dated July 28, 2021.

14. Attached as Exhibit 13 is a true and correct copy of the Deposition of Five Valleys Urology's Rule 30(b)(6) designee John O'Connor.

15. Attached as Exhibit 14 is a true and correct copy of Five Valleys Urology Policy and Procedure Manual.

16. Attached as Exhibit 15 is a true and correct copy of Five Valleys Urology Occupational Safety and Health Administration Manual.

17. Attached as Exhibit 16 is a true and correct copy of the Deposition of Western Montana Clinic's Rule 30(b)(6) designee Meghan Morris.

18. Attached as Exhibit 17 is a true and correct copy of Tamarack Management Employee Handbook

19. Attached as Exhibit 18 is a true and correct copy of Western Montana Clinic's Declination of Influenza Vaccination.

20. Attached as Exhibit 19 is a true and correct copy of Western Montana Clinic's Policy H-7 dated January 1, 2022.

21. Attached as Exhibit 20 is a true and correct copy of Western Montana Clinic's recission of Policy H-7 dated January 13, 2022.

22. Attached as Exhibit 21 is a true and correct copy of Western Montana Clinic's Compliance Manual.

23. Attached as Exhibit 22 is a true and correct copy of Tamarack Management's Compliance Manual.

24. Attached as Exhibit 23 is a true and correct copy of the Deposition of Providence's Rule 30(b)(6) designee Kirk Bodlovic.

25. Attached as Exhibit 24 is a true and correct copy of the Deposition of Providence's Rule 30(b)(6) designee Karyn Trainor.

26. Attached as Exhibit 25 is a true and correct copy of Providence St. Patrick Hospital's Immunization Requirements for Physicians and Allied Health Professionals.

27. Attached as Exhibit 26 is a true and correct copy of the Montana Nurses Association's Response to Defendant's First Discovery Requests.

28. Attached as Exhibit 27 is a true and correct copy of Montana Nurses Association's Position Statements Regarding Vaccinations.

29. Attached as Exhibit 28 is a true and correct copy of the Montana Nurses Association's Membership Survey dated September 2021.

30. Attached as Exhibit 29 is a true and correct copy of the Collective Bargaining Agreement at the Montana Mental Health Nursing Care Center between the State of Montana, Department of Public Health and Human Services and the Montana Nurses Association's dated July 1, 2019-June 30, 2023.

31. Attached as Exhibit 30 is a true and correct copy of the Collective Bargaining Agreement at the Montana Mental Health Nursing

Care Center between the State of Montana, Department of Public Health and Human Services and the Montana Nurses Association's dated March 14, 2016 to June 30, 2019.

32. Attached as Exhibit 31 is a true and correct copy of the Montana Nurses Association's Agenda for a November 18, 2021, zoom call regarding the Centers for Medicare and Medicaid Services COVID-19 Vaccine Mandate.

33. Attached as Exhibit 32 is a true and correct copy of the Joint Commission's Final Accreditation Report for Providence occurring on June 21, 2022 to July 20, 2022.

34. Attached as Exhibit 33 is a true and correct copy of the Declaration of Carter Anderson.

35. Attached as Exhibit 34 is a true and correct copy of the Deposition of the Montana Human Rights Bureau's Rule 30(b)(6) designee Marieke Beck.

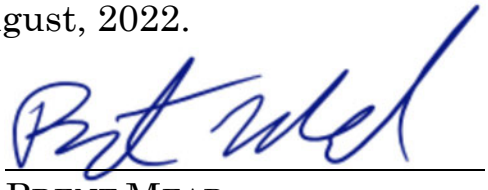
36. Attached as Exhibit 35 are true and correct copies of Providence policies related to Equal Employment Opportunity, Transitional Duty, Influenza Vaccination, Respiratory Protection, and Visitation.

37. Attached as Exhibit 36 is a true and correct copy of Providence St. Patrick Hospital's COVID-19 Plan.

38. Attached as Exhibit 37 is a true and correct copy of the Deposition of David N. Taylor, M.D.

39. Attached as Exhibit 38 is a true and correct copy of the Deposition of David B. King, M.D.

DATED this 26th day of August, 2022.



BRENT MEAD

CERTIFICATE OF SERVICE

I certify that on this date, an accurate copy of the foregoing document was served electronically through the Court's CM/ECF system on registered counsel.

Dated: August 26, 2022

/s/ *Brent Mead*
BRENT MEAD

Exhibit 1

AN ACT PROHIBITING DISCRIMINATION BASED ON A PERSON'S VACCINATION STATUS OR POSSESSION OF AN IMMUNITY PASSPORT; PROVIDING AN EXCEPTION AND AN EXEMPTION; PROVIDING AN APPROPRIATION; AND PROVIDING EFFECTIVE DATES.

WHEREAS, as stated in section 50-16-502, MCA, the Legislature finds that "health care information is personal and sensitive information that if improperly used or released may do significant harm to a patient's interests in privacy and health care or other interests"; and

WHEREAS, the Montana Supreme Court in State v. Nelson, 283 Mont. 231, 941 P.2d 441 (1997), concluded that "medical records fall within the zone of privacy protected by Article II, section 10, of the Montana Constitution" and "are quintessentially private and deserve the utmost constitutional protection".

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Discrimination based on vaccination status or possession of immunity passport prohibited -- definitions. (1) Except as provided in subsection (2), it is an unlawful discriminatory practice for:

(a) a person or a governmental entity to refuse, withhold from, or deny to a person any local or state services, goods, facilities, advantages, privileges, licensing, educational opportunities, health care access, or employment opportunities based on the person's vaccination status or whether the person has an immunity passport;

(b) an employer to refuse employment to a person, to bar a person from employment, or to discriminate against a person in compensation or in a term, condition, or privilege of employment based on the person's vaccination status or whether the person has an immunity passport; or

(c) a public accommodation to exclude, limit, segregate, refuse to serve, or otherwise discriminate against a person based on the person's vaccination status or whether the person has an immunity passport.

(2) This section does not apply to vaccination requirements set forth for schools pursuant to Title 20, chapter 5, part 4, or day-care facilities pursuant to Title 52, chapter 2, part 7.

(3) (a) A person, governmental entity, or an employer does not unlawfully discriminate under this section if they recommend that an employee receive a vaccine.

(b) A health care facility, as defined in 50-5-101, does not unlawfully discriminate under this section if it complies with both of the following:

(i) asks an employee to volunteer the employee's vaccination or immunization status for the purpose of determining whether the health care facility should implement reasonable accommodation measures to protect the safety and health of employees, patients, visitors, and other persons from communicable diseases. A health care facility may consider an employee to be nonvaccinated or nonimmune if the employee declines to provide the employee's vaccination or immunization status to the health care facility for purposes of determining whether reasonable accommodation measures should be implemented.

(ii) implements reasonable accommodation measures for employees, patients, visitors, and other persons who are not vaccinated or not immune to protect the safety and health of employees, patients, visitors, and other persons from communicable diseases.

(4) An individual may not be required to receive any vaccine whose use is allowed under an emergency use authorization or any vaccine undergoing safety trials.

(5) As used in this section, the following definitions apply:

(a) "Immunity passport" means a document, digital record, or software application indicating that a person is immune to a disease, either through vaccination or infection and recovery.

(b) "Vaccination status" means an indication of whether a person has received one or more doses of a vaccine.

Section 2. Exemption. A licensed nursing home, long-term care facility, or assisted living facility is exempt from compliance with [section 1] during any period of time that compliance with [section 1] would result in a violation of regulations or guidance issued by the centers for medicare and medicaid services or the centers for disease control and prevention.

Section 3. Appropriation. There is appropriated $200 from the general fund to the department of labor and industry for the biennium beginning July 1, 2021, for the purposes of:

(1) notifying local boards of health of the requirements of [section 1] and requiring local boards of health to prominently display notice of the requirements of [section 1] on the home page of their website, if available, for at least 6 months after [the effective date of this act]; and

(2) requiring the department of public health and human services to prominently display notice of the requirements of [section 1] on the home page of the department's website for at least 6 months after [the effective date of this act].

Section 4. Codification instruction. [Sections 1 and 2] are intended to be codified as an integral part of Title 49, chapter 2, part 3, and the provisions of Title 49, chapter 2, part 3, apply to [sections 1 and 2].

Section 5. Severability. If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications, the part remains in effect in all valid applications that are severable from the invalid applications.

Section 6. Effective date. (1) Except as provided in subsection (2), [this act] is effective on passage and approval.

(2) [Section 3] is effective July 1, 2021.

- END -

I hereby certify that the within bill,

HB 702, originated in the House.

_____

Chief Clerk of the House

_____

Speaker of the House

Signed this _____day

of_____, 2021.

_____

President of the Senate

Signed this _____day
of_____, 2021.

HOUSE BILL NO. 702

INTRODUCED BY J. CARLSON, D. SKEES, J. READ, D. LENZ, W. GALT, S. BERGLEE, J. HINKLE, M. NOLAND, V. RICCI, B. TSCHIDA, S. GUNDERSON, M. REGIER, L. SHELDON-GALLOWAY, J. TREBAS, D. BARTEL, C. KNUDSEN, B. USHER, J. PATELIS, S. VINTON, M. HOPKINS, F. FLEMING, J. FULLER, R. KNUDSEN, J. KASSMIER, T. MOORE, B. LER, B. PHALEN, F. NAVE, L. BREWSTER, B. MITCHELL, A. REGIER, S. KERNS, S. GALLOWAY, S. GIST, E. HILL, J. SCHILLINGER, K. SEEKINS-CROWE, M. STROMSWOLD, J. GILLETTE, C. HINKLE, M. BINKLEY, R. MARSHALL

AN ACT PROHIBITING DISCRIMINATION BASED ON A PERSON'S VACCINATION STATUS OR POSSESSION OF AN IMMUNITY PASSPORT; PROVIDING AN EXCEPTION AND AN EXEMPTION; PROVIDING AN APPROPRIATION; AND PROVIDING EFFECTIVE DATES.

Exhibit 2

OFFICE OF THE GOVERNOR
STATE OF MONTANA

GREG GIANFORTE
GOVERNOR

KRISTEN JURAS
LT. GOVERNOR

April 28, 2021

The Honorable Wylie Galt
Speaker of the House
State Capitol
Helena, MT 59601

The Honorable Mark Blasdel
President of the Senate
State Capitol
Helena, MT 59601

Dear Speaker Galt and President Blasdel:

"Vaccine passports" undermine individual liberty and threaten personal privacy, tenets Montanans hold dear. No person should be compelled to involuntarily divulge their personal health information as a condition of participating in everyday life, and so-called vaccine passports are one step down a dangerous path that erodes personal privacy. "Vaccine passports" are steeped in discrimination and have no place in our state.

I appreciate the Legislature's work to prohibit "vaccine passports" in Montana with House Bill 702, and I support the sponsor's efforts and intent. However, I believe this measure can be strengthened.

Therefore, in accordance with the power vested in me as Governor by the Constitution and the laws of the State of Montana, I hereby return with amendments House Bill 702: "A BILL FOR AN ACT ENTITLED: "AN ACT PROHIBITING DISCRIMINATION BASED ON A PERSON'S VACCINATION STATUS OR POSSESSION OF AN IMMUNITY PASSPORT; PROVIDING AN EXCEPTION; PROVIDING AN APPROPRIATION; AND PROVIDING EFFECTIVE DATES."

In line with Executive Order 7-2021, I firmly believe that "vaccine passports," or any documentation related to an individual's vaccination status, are an unwarranted infringement on our liberties.

Many Montanans have deeply held religious reasons for not obtaining a vaccine. Others have health conditions that prohibit them from getting one. Ultimately, the decision to receive a vaccine is voluntary, and Montanans should not face the threat of discrimination rooted in whether they decide to receive a vaccine. Furthermore, employers must not discriminate or take punitive action against employees who opt out of immunizations, but instead should work to provide well established, reasonable accommodations that protect the health and safety of all involved.

For these reasons, I am pleased to offer an amendment that strengthens HB 702 and promotes its proper enactment. Specifically, my amendment clarifies that an employer may ask an employee to volunteer their vaccination or immunization status under certain circumstances.

My amendment also makes clear that an employer's implementation of reasonable accommodation measures for persons who are not vaccinated or not immune to protect the safety and health of employees, customers, patients, visitors, and other persons from communicable diseases is not unlawful discrimination.

Additionally, my amendment would ensure that provisions of HB 702 do not put licensed nursing homes, long-term care facilities, or assisted living facilities in violation of regulations or guidance issued by the U.S. Centers for Medicare and Medicaid Services.

This is an important bill that can be reinforced to further protect Montanans, and I respectfully ask for your support of this amendment.

Sincerely,

Greg Gianforte
Governor

Enclosure

cc: Legislative Services Division
Christi Jacobsen, Secretary of State

Amendments to House Bill No. 702
Reference Copy

Requested by the Governor
For the (H) Committee of the Whole

Prepared by Todd Everts
04/28/2021, 08:10:50

1. Title, line 10.
Following: "EXCEPTION"
Insert: "AND AN EXEMPTION"

2. Page 2, line 12.
Following: "~~(3)~~ ~~(2)~~ (3)"
Insert: "(a)"

3. Page 2.
Following: line 13
Insert: "(b) A health care facility, as defined in 50-5-101, does not unlawfully discriminate under this section if it complies with both of the following:
(i) asks an employee to volunteer the employee's vaccination or immunization status for the purpose of determining whether the health care facility should implement reasonable accommodation measures to protect the safety and health of employees, patients, visitors, and other persons from communicable diseases. A health care facility may consider an employee to be nonvaccinated or nonimmune if the employee declines to provide the employee's vaccination or immunization status to the health care facility for purposes of determining whether reasonable accommodation measures should be implemented.
(ii) implements reasonable accommodation measures for employees, patients, visitors, and other persons who are not vaccinated or not immune to protect the safety and health of employees, patients, visitors, and other persons from communicable diseases."

4. Page 2.
Following: line 21
Insert: "NEW SECTION. **Section 2. Exemption**. A licensed nursing home, long-term care facility, or assisted living facility is exempt from compliance with [section 1] during any period of time that compliance with [section 1] would result in a violation of regulations or guidance issued by the centers for medicare and medicaid services or the centers for disease control and prevention."

Renumber: subsequent sections

5. Page 3, line 3.
Strike: "[Section 1] is"
Insert: "[Sections 1 and 2] are"

6. Page 3, line 4.
Strike: "[section 1]"
Insert: "[sections 1 and 2]"

7. Page 3, line 12.
Strike: "2"
Insert: "3"

- END -

Explanation - Note: Because the page and line numbers referred to in these amendment instructions are required to match the page and line numbers of the official bill version being amended, they will not necessarily match the page and line numbers shown in any related Amendments in Context document.

Exhibit 3

Bill Draft Number: LC1472
Bill Type - Number: HB 702
Short Title: Prohibit discrimination based on vaccine status or possessing immunity passport
Primary Sponsor: Jennifer Carlson (R) HD 69
Chapter Number: 418

Bill Actions - **Current Bill Progress:** Became Law

Bill Action Count: 75

Action - Most Recent First	Date	Votes Yes	Votes No	Committee
Chapter Number Assigned	05/07/2021			
(H) Signed by Governor	05/07/2021			
(H) Transmitted to Governor	05/04/2021			
(S) Signed by President	05/04/2021			
(H) Signed by Speaker	05/04/2021			
(C) Printed - Enrolled Version Available	04/30/2021			
(H) Returned from Enrolling	04/30/2021			
(H) Sent to Enrolling	04/29/2021			
(S) Returned to House Concurred in Governor's Proposed Amendments	04/29/2021			
(S) 3rd Reading Governor's Proposed Amendments Adopted	04/29/2021	31	19	
(S) 2nd Reading Governor's Proposed Amendments Adopted	04/29/2021	31	19	
(S) Scheduled for 2nd Reading	04/29/2021			
(H) Transmitted to Senate for Consideration of Governor's Proposed Amendments	04/28/2021			
(H) 3rd Reading Governor's Proposed Amendments Adopted	04/28/2021	64	32	
(H) Scheduled for 3rd Reading	04/28/2021			
(H) 2nd Reading Governor's Proposed Amendments Adopted	04/28/2021	65	35	
(H) Scheduled for 2nd Reading	04/28/2021			
(H) Returned with Governor's Proposed Amendments	04/28/2021			
(H) Transmitted to Governor	04/28/2021			
(S) Signed by President	04/28/2021			

(H) Signed by Speaker	04/28/2021			
(C) Printed - Enrolled Version Available	04/27/2021			
(H) Returned from Enrolling	04/27/2021			
(H) Sent to Enrolling	04/26/2021			
(H) 3rd Reading Passed as Amended by Senate	04/26/2021	67	32	
(H) Scheduled for 3rd Reading	04/26/2021			
(H) 2nd Reading Senate Amendments Concurred	04/26/2021	67	33	
(H) Scheduled for 2nd Reading	04/26/2021			
(S) Returned to House with Amendments	04/23/2021			
(S) 3rd Reading Concurred	04/23/2021	32	18	
(S) Scheduled for 3rd Reading	04/23/2021			
(C) Printed - New Version Available	04/22/2021			
(S) 2nd Reading Concurred as Amended	04/22/2021	31	19	
(S) 2nd Reading Motion to Amend Carried	04/22/2021	29	21	
(S) 2nd Reading Motion to Amend Carried	04/22/2021	30	20	
(S) 2nd Reading Motion to Amend Failed	04/22/2021	25	25	
(S) Scheduled for 2nd Reading	04/22/2021			
(C) Printed - New Version Available	04/20/2021			
(S) Committee Report--Bill Concurred as Amended	04/20/2021			(S) Public Health, Welfare and Safety
(S) Committee Executive Action--Bill Concurred as Amended	04/20/2021	6	3	(S) Public Health, Welfare and Safety
(S) Hearing	04/12/2021			(S) Public Health, Welfare and Safety
(S) Referred to Committee	04/09/2021			(S) Public Health, Welfare and Safety
(S) First Reading	04/06/2021			
(H) Transmitted to Senate	04/06/2021			
(H) 3rd Reading Passed	04/06/2021	62	33	
(H) Scheduled for 3rd Reading	04/06/2021			
(C) Printed - New Version Available	04/01/2021			
(H) 2nd Reading Passed as Amended	04/01/2021	66	34	
(H) 2nd Reading Motion to Amend Carried	04/01/2021	99	1	
(H) Scheduled for 2nd Reading	04/01/2021			
(C) Amendments Available	04/01/2021			
(H) Committee Report--Bill Passed	03/31/2021			(H) Judiciary
(H) Sponsor List Modified	03/31/2021			

(H) Committee Executive Action--Bill Passed	03/31/2021	12	7 (H) Judiciary
(H) Hearing	03/31/2021		(H) Judiciary
(C) Introduced Bill Text Available Electronically	03/29/2021		
(H) First Reading	03/29/2021		
(H) Referred to Committee	03/29/2021		(H) Judiciary
(H) Introduced	03/29/2021		
(C) Draft Delivered to Requester	03/29/2021		
(C) Draft Ready for Delivery	03/26/2021		
(C) Executive Director Final Review	03/26/2021		
(C) Draft Ready for Delivery	03/26/2021		
(C) Draft in Assembly	03/26/2021		
(C) Executive Director Review	03/26/2021		
(C) Bill Draft Text Available Electronically	03/26/2021		
(C) Draft in Final Drafter Review	03/26/2021		
(C) Draft in Input/Proofing	03/26/2021		
(C) Draft to Drafter - Edit Review	03/23/2021		
(C) Draft in Edit	03/23/2021		
(C) Draft in Legal Review	03/23/2021		
(C) Draft to Requester for Review	03/17/2021		
(C) Draft Taken Off Hold	03/05/2021		
(C) Draft On Hold	02/11/2021		
(C) Draft Request Received	12/01/2020		

Sponsor, etc.

Sponsor, etc.	Last Name/Organization	First Name	Mi
Requester	Hinkle	Jedediah	
Drafter	Sandru	Alexis	
Primary Sponsor	Carlson	Jennifer	

Subjects

Description	Revenue/Approp.	Vote Majority Req.	Subject Code
Appropriations (see also: State Finance)	Appropriation	Simple	APP

Health (see also: Health Care Services; Safety)	Simple	HLTH
Local Government (see also: City Subjects; County Subjects)	Simple	LG
Safety (see also: Health)	Simple	SAF
State Government	Simple	STGO

Additional Bill Information

Fiscal Note Probable: No
Preintroduction Required: N
Session Law Ch. Number: 418
DEADLINE
Category: Appropriation Bills
Transmittal Date: 04/08/2021
Return (with 2nd house amendments) Date: 04/29/2021

Section Effective Dates

Section(s)	Effective Date	Date Qualified
Sections 1,2, and 4-6	07-MAY-21	
Section 3	01-JUL-21	

(available online at: http://laws.leg.mt.gov/legprd/LAW0203W$BSRV.ActionQuery?P_SESS=20211&P_BLTP_BILL_TYP_CD=HB&P_BILL_NO=702&P_BILL_DFT_NO=&P_CHPT_NO=&Z_ACTION=Find&P_ENTY_ID_SEQ2=&P_SBJT_SBJ_CD=&P_ENTY_ID_SEQ=&P_PRNT_FRNDLY_PG=Y)

Exhibit 4

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 71 / No. 16
April 22, 2022

Vaccination Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2020–21 School Year

Ranee Seither, MPH[1]; Jessica Laury, MPH[1,2]; Agnes Mugerwa-Kasujja, MD[1,3]; Cynthia L. Knighton[1]; Carla L. Black, PhD[1]

State and local school vaccination requirements serve to protect students against vaccine-preventable diseases (*1*). This report summarizes data collected for the 2020–21 school year by state and local immunization programs* on vaccination coverage among children in kindergarten in 47 states and the District of Columbia (DC), exemptions for kindergartners in 48 states and DC, and provisional enrollment or grace period status for kindergartners in 28 states. Vaccination coverage† nationally was 93.9% for 2 doses of measles, mumps, and rubella vaccine (MMR); 93.6% for the state-required number of doses of diphtheria, tetanus, and acellular pertussis vaccine (DTaP); and 93.6% for the state-required doses of varicella vaccine. Compared with the 2019–20 school year, vaccination coverage decreased by approximately one percentage point for all vaccines. Although 2.2% of kindergartners had an exemption from at least one vaccine,§ an additional 3.9% who did not have a vaccine exemption were not up to date for MMR. The COVID-19 pandemic affected schools' vaccination requirement and provisional enrollment policies, documentation, and assessment activities. As schools continue to return to in-person learning, enforcement of vaccination policies and follow-up with undervaccinated students are important to improve vaccination coverage.

To meet state and local school entry requirements, parents submit children's vaccination or exemption documentation to schools, or schools obtain records from state immunization information systems. Federally funded immunization programs work with departments of education, school nurses, and other school personnel to assess vaccination and exemption status of children enrolled in public and private kindergartens and to report unweighted counts, aggregated by school type, to CDC via a web-based questionnaire in the Secure Access Management System, a federal, web-based system that gives authorized personnel secure access to public health applications operated by CDC. CDC uses these counts to produce state-level and national-level estimates of vaccination coverage.

* Federally funded immunization programs are located in 50 states and DC, five cities, and eight U.S territories and freely associated states (territories). Two cities reported data to CDC, which were also included in data submitted by their state. State-level data were used to calculate national estimates and medians. Immunization programs in territories reported vaccination coverage and exemptions; however, these data were not included in national calculations.

† National and median vaccination coverage was determined using estimates for 47 states and DC; Alaska, Illinois, and West Virginia did not report school coverage data because of the impact of COVID-19 on data collection. Data from cities were included with their state data. Data from territories were not included in national and median calculations.

§ National and median exemption rates were determined using estimates for 48 states and DC; Colorado, Minnesota, and Missouri did not collect information on the number of kindergartners with an exemption but instead reported the number of exemptions for each vaccine, which could count some children more than once. For these states, the percentage of kindergartners exempt from the vaccine with the highest number of exemptions (the lower bound of the potential range of exemptions) was included in the national and median exemption rates. Washington was unable to deduplicate students with both religious and philosophical exemptions, so the nonmedical exemption type with the highest number of kindergartners (the lower bound of the potential range of nonmedical exemptions) was included in the national and median exemption rates for nonmedical exemptions. Illinois and West Virginia did not report school vaccine exemption data because of the impact of COVID-19 on data collection. Data from cities were included with their state data. Data from territories were not included in national estimates.

INSIDE

Continuing Education examination available at https://www.cdc.gov/mmwr/mmwr_continuingEducation.html

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

During the 2020–21 school year, 47 states and DC reported coverage for all state-required vaccines among public and private school kindergartners;[¶] 48 states and DC reported exemption data on public school kindergartners and 47 states and DC on private school kindergartners. Overall national and median vaccination coverage for the state-required number of doses of DTaP, MMR, and varicella vaccine are reported. Hepatitis B and poliovirus vaccination coverage, not included in this report, are available at SchoolVaxView (*2*). Twenty-eight states reported the number of kindergartners who were attending school under a grace period (attendance without proof of complete vaccination or exemption during a set interval) or provisional enrollment (school attendance while completing a catch-up vaccination schedule). Thirty states and DC reported the number of kindergartners who had no documentation of any vaccinations or exemptions. Seventeen states reported the number of kindergartners who were out of compliance; these kindergartners did not have complete documentation of having received all required vaccinations but were not eligible for provisional enrollment and did not have documented exemptions for the missing vaccinations. This measure includes those with no documentation at all. All counts were current as of the time of the assessment.[**] National estimates, medians, and summary measures include only U.S. states and DC. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[††]

Vaccination coverage and exemption estimates were adjusted according to survey type and response rate.[§§] National estimates measure coverage and exemptions among all kindergartners, whereas medians measure the midpoint of state-level

[¶] Nine states reported coverage and exemption data for at least some homeschooled kindergartners. Alaska and North Dakota reported some homeschool data separately. California included data for students who attend virtual, partial, or full charter schools with some or all online instruction and students receiving individualized education program services who are medically unable to attend school in public school data. California also included data for homeschools with six or more students in private school data. Montana reported homeschooled students in public school data if the students also attend classes or extracurricular activities at a public school. New Mexico and Pennsylvania included all homeschooled students in public school data. Oregon reported data for students enrolled in exclusively online homeschool programs separately; online students of otherwise traditional public schools were included in public school data. South Carolina and Wisconsin include homeschooled students in their public and private school data if the students also attend classes, extracurricular activities, or have other contact with a school.

[**] Assessment date varied by state and area. Four states were assessed on the first day of school; 13 states were assessed by December 31; 17 states and DC were assessed by some other date, ranging from 30 days after admission to June 23, 2021; and 16 states were assessed on a rolling basis. Maryland ended data collection early because of COVID-19 response activities.

[††] 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

[§§] A majority of immunization programs that used census or voluntary response provided CDC with data aggregated at the state or local (city or territory) level. Coverage and exemption data based on a census or voluntary response were adjusted for nonresponse using the inverse of the response rate, stratified by school type (public, private, and homeschool, where available). Programs that used complex sample surveys provided CDC with deidentified data aggregated at the school or county level for weighted analysis. Weights were calculated to account for sample design and adjusted for nonresponse for data collected through complex sample design wherever possible.

The *MMWR* series of publications is published by the Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested citation: [Author names; first three, then et al., if more than six.] [Report title]. MMWR Morb Mortal Wkly Rep 2022;71:[inclusive page numbers].

coverage regardless of population size. During the 2020–21 school year, 3,520,205 children in 48 states and DC were reported by immunization programs as enrolled in kindergarten.¶¶ Reported estimates are based on 3,187,569 of these kindergartners who were surveyed for vaccination coverage; 3,337,916 for exemptions; 2,467,326 for grace period and provisional enrollment; 1,799,190 for documentation; and 1,049,075 for compliance. Kindergarten enrollment reported by the 48 states and DC was approximately 10% lower than that reported for the 2019–20 school year by 48 states. Potentially achievable coverage with MMR, defined as the sum of the percentage of children who were up to date with 2 doses of MMR and those with no documented vaccination exemption but not up to date, was calculated for each state. Nonexempt students include those who were provisionally enrolled in kindergarten, in a grace period, or otherwise without documentation of complete vaccination. SAS software (version 9.4; SAS Institute) was used for all analyses.

Vaccination assessments varied by state because of differences in required vaccines and doses, vaccines assessed, methods of data collection, and data reported (Supplementary Table 1, https://stacks.cdc.gov/view/cdc/116354). Kindergartners were considered up to date for a given vaccine if they received all doses of that vaccine required for school entry,*** except in nine states††† that reported kindergartners as up to date for any given vaccine only if they received all doses of all vaccines required for school entry. States were asked to report any COVID-19–related impact on kindergarten vaccination measurement and coverage.

Nationally, 2-dose MMR coverage was 93.9% (median = 93.7%; range = 78.9% [DC] to ≥98.9% [Mississippi]). Coverage ≥95% was reported by 16 states and <90% by 7 states and DC (Table). DTaP coverage was 93.6% (range = 78.5% [DC] to ≥98.9% [Mississippi]). Coverage ≥95% was reported by 16 states, and coverage <90% by eight states and DC. Varicella vaccine coverage nationally was 93.6% (range = 78.0% [DC] to ≥98.9% [Mississippi]), with 17 states reporting coverage ≥95% and nine states and DC reporting <90% coverage.

The percentage of kindergartners with an exemption for ≥1 required vaccines (not limited to MMR, DTaP, and varicella vaccines) was 2.2% in 2020–21 (range = 0.1% [Mississippi and New York] to 8.2% [Idaho]), similar to the 2.5% reported during the 2019–20 school year (Table). Nationally, 0.2% of kindergartners had a medical exemption and 1.9% had a nonmedical exemption (Supplementary Table 2, https://stacks.cdc.gov/view/cdc/116355). The percentage of kindergartners provisionally enrolled in kindergarten or within a grace period among the 28 states reporting these data was 2.0% (range = 0.1% [Hawaii] to 10.0% [Arkansas]) (Table).

Among states that reported data for both 2019–20 and 2020–21, MMR coverage and exemptions for ≥1 vaccines decreased in approximately 75% of states; grace period or provisional enrollment increased in 18 of the 28 states reporting this measure (Figure 1). The proportion of students who were not fully vaccinated and not exempt increased in a majority of states. Among states reporting these measures in 2020–21, the proportion of kindergartners attending school with no documentation of required vaccinations or exemptions ranged from 0.1% (Pennsylvania and Virginia) to 8.3% (Maryland); the proportion out of compliance with school requirements ranged from 0.2% (Florida) to 16.6% (Indiana) (Table). Among the 33 states and DC with MMR coverage <95%, all but two could potentially achieve ≥95% MMR coverage if all nonexempt kindergartners who were within a grace period, provisionally enrolled, or out of compliance received vaccination (Figure 2).

Discussion

During the 2020–21 school year, vaccination coverage among kindergartners nationwide was lower than during the 2019–20 school year at approximately 94% (*2*,*3*) for MMR, DTaP, and varicella vaccines, a level just under the target of 95%; coverage for all three vaccines decreased in a majority of states. National MMR coverage among kindergartners fell below the Healthy People 2030 target of 95% (*4*). Reported enrollment and response rates also decreased nationally and in a majority of states (*3*). Some of the decreases in enrollment could be because of schools not reporting these data to state immunization programs, or parents might have decided to have the child delay or skip the kindergarten year. The kindergarten assessment for the 2021–22 school year will include these students if they are enrolled in kindergarten for the 2021–22

¶¶ These totals are the summations of the kindergartners surveyed among programs reporting data for coverage, exemptions, grace periods, and provisional enrollment. Data from cities and territories were not included in these totals.

*** All states required 2 doses of a measles-containing vaccine. Six states (Georgia, New Jersey, New York, North Carolina, Oregon, and Virginia) require only 1 dose of rubella vaccine. New Jersey and Oregon require only 1 dose of mumps vaccine, and mumps vaccine is not required in Iowa. Local DTaP requirements varied. Nebraska required 3 doses of DTaP, two states (Maryland and Wisconsin) required 4 doses, and all other states required 5 doses, unless dose 4 was administered on or after the fourth birthday. The reported coverage estimates represent the percentage of kindergartners with the state-required number of DTaP doses, except for Kentucky, which required 5 doses of DTaP by age 5 years but reported 4-dose coverage for kindergartners. Two states (Maryland and Nebraska) require only 3 doses of polio vaccine, all other states require 4 doses unless the last dose was given on or after the fourth birthday. Six states required 1 dose of varicella vaccine; 44 states and DC required 2 doses.

††† Alabama, Florida, Georgia, Iowa, Mississippi, New Hampshire, New Jersey, Wisconsin, and Wyoming considered kindergartners up to date only if they had received all doses of all vaccines required for school entry.

TABLE. Estimated* vaccination coverage† for measles, mumps, and rubella vaccine, diphtheria, tetanus, and acellular pertussis vaccine, and varicella vaccine, grace period or provisional enrollment,§ and any exemption¶, among kindergartners, by immunization program — United States,†† 2020–21 school year**

Immunization program	Kindergarten population§§	% Surveyed¶¶	% Vaccine doses			% Grace period or provisional enrollment	% Any exemption	Percentage point change in any exemption from 2019–20 school year	% No documentation¶¶¶	% Out of compliance****
			2 of MMR***	5 of DTaP†††	2 of varicella§§§					
National estimate††††	**3,520,205**	**90.8**	**93.9**	**93.6**	**93.6**	**2.0**	**2.2**	**−0.3**	**1.0**	**3.4**
Median††††	**NA**	**NA**	**93.7**	**93.4**	**93.7**	**2.1**	**2.5**	**−0.2**	**0.7**	**2.8**
Alabama§§§§,¶¶¶¶	56,974	100.0	≥94.7	≥94.7	≥94.7	NP	1.3	0.1	NR	3.7
Alaska¶¶¶¶,*****	9,461	92.5	NR	NR	NR	NR	4.0	−1.9	NR	NR
Arizona†††††	76,382	93.4	91.9	92.0	95.5	NR	5.5	0.0	NR	0.6
Arkansas§§§§§	37,540	95.6	93.2	92.3	92.8	10.0	2.0	0.1	1.2	NR
California¶¶¶¶,†††††,§§§§§	498,214	97.5	95.1	94.7	94.8	0.7	0.5	−0.3	NR	NR
Colorado	63,619	97.3	90.5	90.1	89.4	0.5	≥4.2	−0.7	NR	NR
Connecticut§§§§,¶¶¶¶	34,396	100.0	95.3	95.3	95.1	NP	2.6	0.1	NR	NR
Delaware¶¶¶¶	10,587	9.2	95.7	94.9	95.3	NR	2.4	NA	0.5	6.1
DC§§§§,¶¶¶¶	8,262	100.0	78.9	78.5	78.0	NR	0.3	NA	4.8	NR
Florida§§§§,¶¶¶¶	207,026	100.0	≥93.3	≥93.3	≥93.3	3.4	3.1	−0.3	NR	0.2
Georgia§§§§,¶¶¶¶	83,191	100.0	≥88.5	≥88.5	≥88.5	0.6	2.9	−0.1	1.0	NR
Hawaii¶¶¶¶	13,074	9.3	90.7	91.3	87.2	0.1	3.7	−2.4	0.9	NR
Idaho	22,677	98.3	86.5	86.4	86.2	1.5	8.2	0.6	1.2	7.2
Illinois¶¶¶¶	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Indiana¶¶¶¶,******	78,694	71.4	93.1	83.9	92.8	NR	1.9	−0.3	0.7	16.6
Iowa§§§§,¶¶¶¶	39,141	100.0	≥93.4	≥93.4	≥93.4	3.1	2.2	−0.3	NR	1.3
Kansas¶¶¶¶,§§§§§,¶¶¶¶¶,******	34,687	32.7	92.6	90.8	91.8	NR	2.0	−0.1	1.3	NR
Kentucky¶¶¶¶,§§§§§,******	59,233	86.4	88.9	89.4	88.3	NR	1.0	−0.8	5.9	NR
Louisiana§§§§	61,912	100.0	96.2	96.9	93.2	NP	1.1	−0.4	0.3	NR
Maine	13,477	85.0	94.3	94.0	97.0	NR	4.5	−1.4	2.6	NR
Maryland¶¶¶¶,§§§§§	65,764	75.6	87.6	89.7	87.3	NR	0.9	−0.5	8.3	NR
Massachusetts§§§§,¶¶¶¶,§§§§§	60,724	100.0	95.9	95.7	95.4	NP	1.1	−0.2	0.7	5.1
Michigan§§§§	106,657	100.0	94.6	95.4	94.2	0.4	3.7	−0.7	0.2	2.8
Minnesota†††††	66,007	95.2	89.8	89.3	89.0	NR	≥2.8	−1.0	NR	NR
Mississippi§§§§,¶¶¶¶,†††††	34,028	100.0	≥98.9	≥98.9	≥98.9	0.6	0.1	−0.1	0.3	NR
Missouri§§§§,¶¶¶¶	63,093	100.0	92.6	92.6	92.1	NR	≥2.5	−0.2	1.1	NR
Montana§§§§,¶¶¶¶	11,279	100.0	92.9	91.9	91.9	2.0	3.5	−0.8	1.1	NR
Nebraska¶¶¶¶,§§§§§	25,681	94.8	95.5	96.1	95.1	2.7	2.2	0.0	NR	NR
Nevada¶¶¶¶	34,171	94.7	96.1	95.4	95.8	2.1	4.4	0.4	NR	4.1
New Hampshire¶¶¶¶,******	10,242	57.0	≥90.8	≥90.8	≥90.8	4.7	2.8	−0.3	NR	1.7
New Jersey§§§§,¶¶¶¶	100,144	100.0	≥94.3	≥94.3	≥94.3	1.2	2.2	−0.4	NR	2.2
New Mexico§§§§,¶¶¶¶	20,589	100.0	95.7	95.7	95.3	6.3	0.9	−0.6	0.5	NR
New York (including New York City) ¶¶¶¶,†††††	216,804	91.5	98.3	97.8	98.1	1.0	0.1	0.0	0.2	NR
New York City¶¶¶¶,†††††	91,920	94.2	97.4	96.6	97.1	0.9	<0.1	0.0	0.4	NR
North Carolina¶¶¶¶,§§§§§,******	120,995	89.0	95.2	95.2	95.1	1.7	1.5	−0.2	NR	2.6
North Dakota	10,116	99.1	93.3	93.1	93.2	NR	4.2	0.3	0.9	NR
Ohio	128,535	91.1	89.6	89.0	88.7	7.1	2.5	−0.3	1.8	NR
Oklahoma§§§§§	52,656	90.0	90.5	90.3	96.1	NR	2.4	−0.3	1.0	NR
Oregon§§§§,§§§§§	39,568	100.0	92.7	91.6	95.1	NR	5.4	−1.7	0.6	NR
Pennsylvania	129,307	95.0	95.5	95.9	95.3	3.8	2.7	−0.3	0.1	NR
Rhode Island¶¶¶¶,§§§§§,******	10,402	93.0	97.0	96.8	96.7	NR	1.0	−0.3	0.5	NR
South Carolina¶¶¶¶,¶¶¶¶¶	56,330	26.5	94.4	95.0	94.2	3.9	2.4	−0.2	0.7	NR
South Dakota¶¶¶¶	11,512	99.9	94.6	93.7	94.0	NR	3.4	0.7	NR	NR
Tennessee§§§§,¶¶¶¶,******	73,819	100.0	96.6	96.4	96.4	1.0	1.9	−0.1	0.5	NR
Texas (including Houston) §§§§§,******	377,840	98.9	95.3	95.0	95.0	1.1	2.3	−0.2	0.3	NR
Houston, Texas§§§§§,******	39,627	94.9	83.7	83.9	83.1	0.3	1.3	−0.2	0.7	NR
Utah§§§§	46,247	100.0	91.4	91.1	91.2	4.1	5.1	−0.3	0.5	1.7
Vermont§§§§,¶¶¶¶	5,535	100.0	94.0	93.6	93.3	5.4	3.2	−0.5	NR	NR
Virginia¶¶¶¶,¶¶¶¶¶	88,273	2.0	95.8	97.7	94.1	NR	1.5	−0.2	0.1	NR
Washington§§§§,******	74,931	100.0	94.4	93.2	93.2	0.6	3.3	−1.3	NR	5.0
West Virginia¶¶¶¶,†††††	NR	NA	NR	NR	NR	NR	NR	NA	NR	NR
Wisconsin§§§§§,******	63,486	84.5	≥87.2	≥87.2	≥87.2	5.1	5.2	−0.5	0.6	3.1
Wyoming§§§§,¶¶¶¶	6,923	100.0	≥90.2	≥90.2	≥90.2	2.4	3.0	−0.5	NR	2.1
Territories and freely associated states										
American Samoa¶¶¶¶,††††††	1,045	100.0	87.7	65.2	56.3	NR	0.0	0.0	NR	NR
Federated States of Micronesia	1,604	96.6	98.4	86.1	Nreq	NR	NR	NA	NR	NR
Guam	NR	NA	NR	NR	NR	NR	NR	NA	NR	NR

See table footnotes on the next page.

TABLE. (*Continued*) Estimated* vaccination coverage† for measles, mumps, and rubella vaccine, diphtheria, tetanus, and acellular pertussis vaccine, and varicella vaccine, grace period or provisional enrollment,§ and any exemption¶, among kindergartners, by immunization program — United States,†† 2020–21 school year**

Immunization program	Kindergarten population§§	% Surveyed¶¶	% Vaccine doses: 2 of MMR***	% Vaccine doses: 5 of DTaP†††	% Vaccine doses: 2 of varicella§§§	% Grace period or provisional enrollment	% Any exemption	Percentage point change in any exemption from 2019–20 school year	% No documentation¶¶¶	% Out of compliance****
Marshall Islands¶¶¶¶,†††††	1,016	100.0	99.7	94.4	Nreq	NR	NR	NA	NR	NR
Northern Mariana Islands§§§§	830	100.0	94.5	84.2	95.3	NR	0.0	0.0	NR	NR
Palau	NR	NA	NR	NR	NR	NR	NR	NA	NR	NR
Puerto Rico¶¶¶¶	26,353	NA	NR	NR	NR	NR	NR	NA	NR	NR
U.S. Virgin Islands	NR	NA	NR	NR	NR	NR	NR	NA	NR	NR

Abbreviations: DC = District of Columbia; DTaP = diphtheria, tetanus, and acellular pertussis vaccine; MMR = measles, mumps, and rubella vaccine; NA = not available; NP = no grace period or provisional policy; NR = not reported to CDC; Nreq = not required.

* Estimates adjusted for nonresponse and weighted for sampling where appropriate.

† Estimates based on a completed vaccine series (i.e., not vaccine specific) use the "≥" symbol. Coverage might include history of disease or laboratory evidence of immunity.

§ A grace period is a set number of days during which a student can be enrolled and attend school without proof of complete vaccination or exemption. Provisional enrollment allows a student without complete vaccination or exemption to attend school while completing a catch-up vaccination schedule. In states with one or both of these policies, the estimates represent the number of kindergartners who were within a grace period, were provisionally enrolled, or were in a combination of these categories.

¶ Some programs did not report the number of children with exemptions, but instead reported the number of exemptions for each vaccine, which could count some children more than once. Lower bounds of the percentage of children with any exemptions were estimated using the individual vaccines with the highest number of exemptions. Estimates based on vaccine-specific exemptions use the "≥" symbol.

** Exemptions, grace period or provisional enrollment, and vaccine coverage status might not be mutually exclusive. Some children enrolled under a grace period or provisional enrollment might be exempt from ≥1 vaccinations, and children with exemptions might be fully vaccinated with ≥1 required vaccines.

†† Includes five territories and three freely associated states.

§§ The kindergarten population is an approximation provided by each program.

¶¶ The number surveyed represents the number surveyed for coverage, except in Alaska. The national number does not include Alaska, which did not report coverage but surveyed 8,756 students for exemptions. In other jurisdictions, exemption estimates are based on 27,421 kindergartners for Kansas, 56,330 for South Carolina, 85,873 for Virginia, and 39,627 for Houston.

*** A majority of states require 2 doses of MMR; Alaska, New Jersey, and Oregon require 2 doses of measles, 1 dose of mumps, and 1 dose of rubella vaccines. Georgia, New York, New York City, North Carolina, and Virginia require 2 doses of measles and mumps vaccines and 1 dose of rubella vaccine. Iowa requires 2 doses of measles vaccine and 2 doses of rubella vaccine.

††† Pertussis vaccination coverage might include some DTP vaccinations if administered in another country. A majority of states require 5 doses of DTaP for school entry or 4 doses if the fourth dose was received on or after the fourth birthday; Maryland requires 4 doses and Nebraska requires 3 doses. The reported coverage estimates represent the percentage of kindergartners with the state-required number of DTaP doses, except for Kentucky, which requires 5 doses of DTaP by age 5 years but reported 4-dose coverage for kindergartners.

§§§ A majority of states require 2 doses of varicella vaccine for school entry; Alabama, Arizona, California, Hawaii, Maine, New Jersey, Oklahoma, and Oregon require 1 dose. Reporting of varicella vaccination status for kindergartners with a history of varicella disease varied within and among states; some kindergartners were reported as vaccinated against varicella and others as medically exempt.

¶¶¶ Estimates represent the number of kindergartners with no documentation of any vaccinations or exemptions.

**** Students were considered out of compliance if they did not have complete documentation of having received all required vaccinations but were not eligible for provisional enrollment and did not have documented exemptions for the missing vaccinations. This measure included those with no documentation at all.

†††† National coverage estimates and medians were calculated using data from 47 states (i.e., does not include Alaska, Illinois, or West Virginia) and DC. National grace period or provisional enrollment estimates and median were calculated using data from the 28 states that have either a grace period or provisional enrollment policy and reported relevant data to CDC. National exemption estimate and median were calculated from data from 48 states (i.e., did not include Illinois or West Virginia) and DC. Other jurisdictions excluded were Houston, New York City, American Samoa, Guam, Marshall Islands, Federated States of Micronesia, Northern Mariana Islands, Palau, Puerto Rico, and the U.S. Virgin Islands. National estimate and median were calculated using data from 30 states and DC for kindergartners with no documentation, and 17 states for kindergartners who were out of compliance. Data reported from 3,187,569 kindergartners were assessed for coverage, 3,337,916 for exemptions, 2,467,326 for grace period or provisional enrollment, 1,799,190 for no documentation, and 1,049,075 for out of compliance. Estimates represent rates for populations of coverage (3,510,744), exemptions (3,520,205), grace period or provisional enrollment (2,608,025), no documentation (2,190,919), and out of compliance (1,109,078).

§§§§ The proportion surveyed likely was <100% but is reported as 100% based on incomplete information about the actual current enrollment.

¶¶¶¶ Philosophical exemptions were not allowed.

***** Alaska did not report kindergarten vaccination coverage because of problems with data collection. Vaccination coverage among children aged 63–75 months in VacTrAK, Alaska's Immunization Information System, was 70.2% for MMR, 83.0% for DTaP, and 67.1% for varicella vaccine.

††††† Religious exemptions were not allowed.

§§§§§ Counted some or all vaccine doses received regardless of Advisory Committee on Immunization Practices recommended age and time interval; vaccination coverage rates reported might be higher than those for valid doses.

¶¶¶¶¶ Vaccination coverage data were collected from a sample of kindergartners; exemption data were collected from a census of kindergartners.

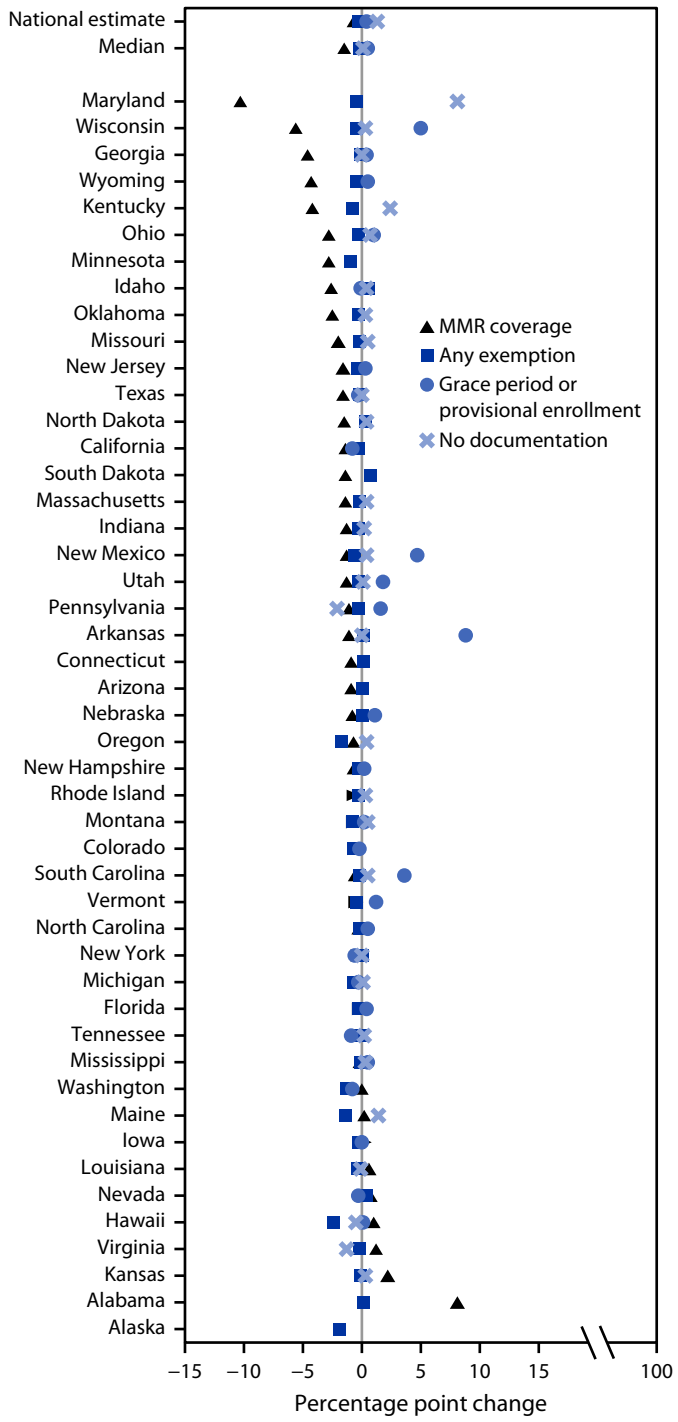
****** Did not include certain types of schools, such as kindergartens in child care facilities, online schools, correctional facilities, or those located on military bases or tribal lands.

†††††† Reported exemption data for public schools only.

school year, but not if they were enrolled in first grade for the 2021–22 school year.

The overall percentage of children with an exemption remained low during the 2020–21 school year at 2.2%; the percentage of children with exemptions decreased in 37 states. Nonexempt undervaccinated students often attend school while in a grace period or are provisionally enrolled; in many states, these policies were expanded either formally or informally during the 2020–21 school year. States described reluctance to schedule and reduced access to well-child appointments, expanded grace period or provisional enrollment, and easing of vaccination requirements for remote learners, reduced submission of documentation by parents, less time for school nurses to follow-up with students missing documentation or vaccines, fewer staff members to conduct kindergarten vaccination coverage assessment and reporting activities, lower response rates from schools, and both extended and compressed kindergarten vaccination coverage data collection schedules, all related to COVID-19 (CDC, School Vaccination Coverage Report, unpublished data, 2021). During the 2020–21 school

FIGURE 1. Change in measles, mumps, and rubella vaccine coverage, any exemption, grace period or provisional enrollment, and no documentation* among kindergartners, by state — 47 states,† 2019–20 to 2020–21 school year



Abbreviation: MMR = measles, mumps, and rubella vaccine.

* States are sorted from lowest to highest by change in MMR coverage (n = 46), any exemption (n = 47), grace period or provisional enrollment (n = 28), and no documentation (n = 29). Not all states reported data for all categories.

† Delaware and District of Columbia did not report for any categories for the 2019–20 school year, and Illinois and West Virginia did not report for any categories for the 2020–21 school year. All were excluded from this analysis.

Summary

What is already known about this topic?

State immunization programs conduct annual kindergarten vaccination assessments to monitor school entry vaccination coverage with all state-required vaccines.

What is added by this report?

For the 2020–21 school year, coverage was approximately 94% for all required vaccines, approximately one percentage point lower than the previous school year. The exemption rate remained low at 2.2%.

What are the implications for public health practice?

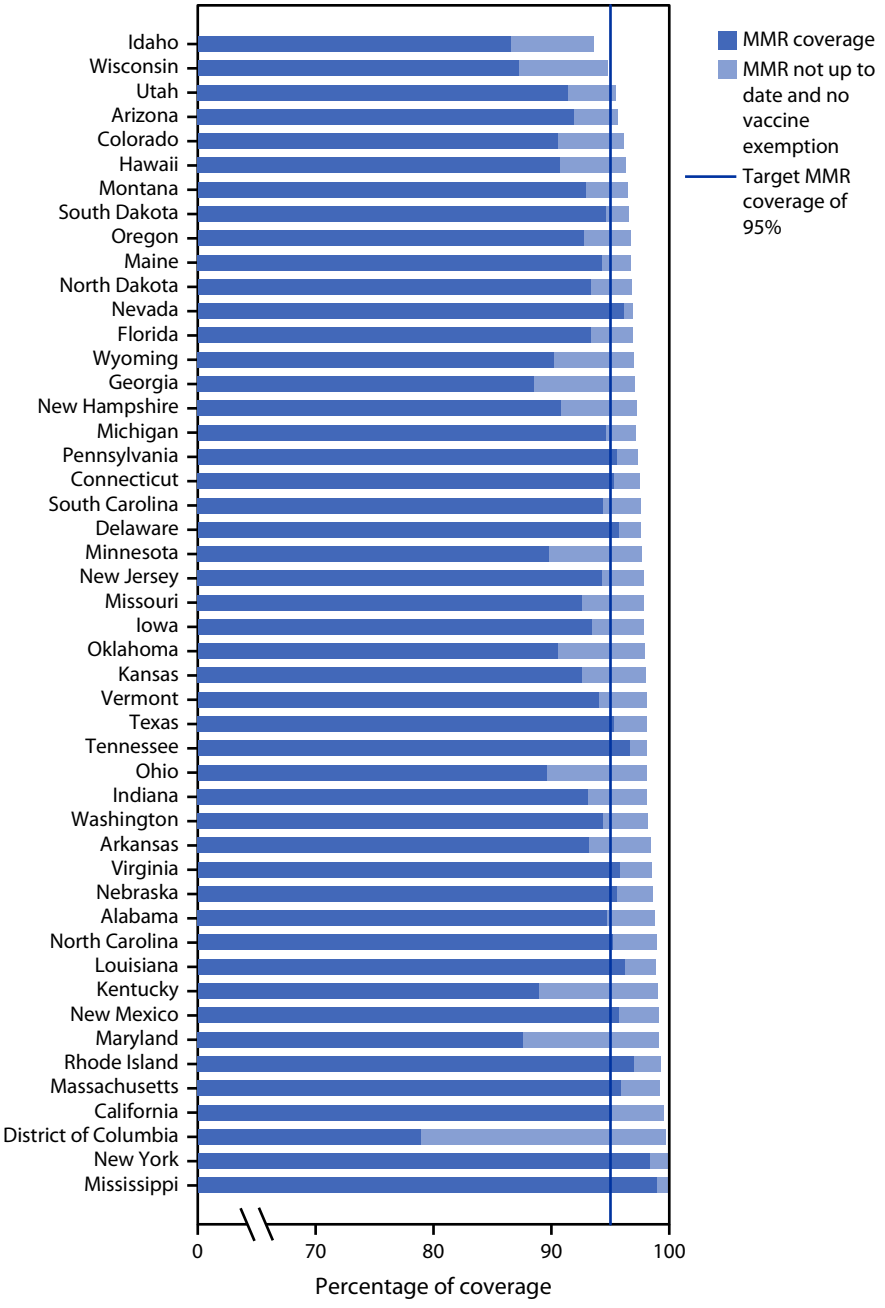
Disruptions caused by COVID-19 reduced reported enrollment, school response rates, and documentation for the 2020–21 school year. Schools and immunization programs can increase follow-up with undervaccinated students to reduce the impact of COVID-19–associated disruptions on vaccination coverage to protect students during the return to in-person learning.

year, 10% of school principals reported that fewer students were fully vaccinated in that school year.§§§ Twenty-seven percent of school nurses reported that fewer students were fully vaccinated in the 2020–21 school year, and 46% of school nurses reported that school vaccination requirements were a somewhat lower or much lower priority compared with previous years (CDC, Impact of the COVID-19 Pandemic on K–12 School Nurses 2020/2021 School Year, unpublished data, 2021). Decreases in vaccine ordering and administration during 2020 also support the measured decreases in coverage (*5–8*).

The findings in this report are subject to at least five limitations. First, comparison between states is limited because of variation in states' requirements such as vaccine required, number of doses required, date required, and type of documentation accepted; data collection methods; exemptions allowed; and definitions of grace period and provisional enrollment. Second, representativeness might be negatively affected because of data collection methods that assess vaccination status at different times or miss some schools or students, such as students who were homeschooled. Third, vaccination coverage, exemption rates, or both might be underestimated or overestimated because of inaccurate or absent documentation or missing schools. Fourth, national coverage estimates for the 2020–21 school year include only 47 of 50 states and DC but use lower-bound estimates for nine states; exemption estimates include 48 states and DC but use lower-bound estimates for four states, and grace period or provisional enrollment estimates include only 28 states. Finally, the COVID-19 pandemic response created various barriers that limited the amount and quality of student vaccination data collected and reported

§§§ https://www.cdcfoundation.org/vaccine-triangulation-report?inline

FIGURE 2. Potentially achievable coverage*,† with measles, mumps, and rubella vaccine among kindergartners, by state — 47 states§ and District of Columbia, 2020–21 school year



Abbreviation: MMR = measles, mumps, and rubella vaccine.

* States are ranked from lowest to highest by potentially achievable coverage. Potentially achievable coverage was estimated as the sum of the percentage of students with up-to-date MMR and the percentage of students without up-to-date MMR and without a documented vaccine exemption.

† The exemptions used to calculate the potential increase in MMR coverage for Arizona, Arkansas, Colorado, District of Columbia, Idaho, Maine, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, Texas, Utah, Vermont, and Wisconsin were the number of children with exemptions specifically for MMR vaccine. For all other states, numbers were based on an exemption to any vaccine.

§ Alaska, Illinois, and West Virginia did not report kindergarten vaccination coverage for the 2020–21 school year and are excluded from this analysis.

by local health departments. These barriers included schools closing or shifting to virtual learning, many states effectively easing vaccination requirements, and the reassigning of state and local health departments' staff members to response activities.

Among children aged 4–6 years, vaccination coverage is higher among those in kindergarten than among those not yet in kindergarten (*9*). Although coverage among kindergartners was lower in the 2020–21 school year than in 2019–20 for all reported vaccines, vaccination coverage might be lower among kindergarten-age children whose school entry has been delayed. Vaccination coverage could be improved by increased outreach by schools and immunization programs to first-time students, including kindergartners and first graders, and by follow-up with undervaccinated students. As schools return to in-person learning, high vaccination coverage is necessary to continue protecting students from vaccine-preventable diseases.

Acknowledgment

CDC Foundation's COVID-19 Emergency Response.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 483

[CMS–3414–IFC]

RIN 0938–AU57

Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs–IID) Residents, Clients, and Staff

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) revises the infection control requirements that long-term care (LTC) facilities (Medicaid nursing facilities and Medicare skilled nursing facilities, also collectively known as ''nursing homes'') and intermediate care facilities for individuals with intellectual disabilities (ICFs–IID) must meet to participate in the Medicare and Medicaid programs. This IFC aims to reduce the spread of SARS–CoV–2 infections, the virus that causes COVID–19, by requiring education about COVID–19 vaccines for LTC facility residents, ICF–IID clients, and staff serving both populations, and by requiring that such vaccines, when available, be offered to all residents, clients, and staff. It also requires LTC facilities to report COVID–19 vaccination status of residents and staff to the Centers for Disease Control and Prevention (CDC). These requirements are necessary to help protect the health and safety of ICF–IID clients and LTC facility residents. In addition, the rule solicits public comments on the potential application of these or other requirements to other congregate living settings over which CMS has regulatory or other oversight authority.

DATES: These regulations are effective on May 21, 2021.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 12, 2021.

ADDRESSES: In commenting, please refer to file code CMS–3414–IFC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3414–IFC, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3414–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Diane Corning, (410) 786–8486, Lauren Oviatt, (410) 786–4683, Kim Roche, (410) 786–3524, or Kristin Shifflett, (410) 786–4133, for all rule related issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Currently, the United States (U.S.) is responding to a public health emergency 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). On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of International Concern.'' On January 31, 2020, pursuant to section 319 of the Public Health Service Act (PHSA) (42 U.S.C. 247d), the Secretary of the Department of Health and Human Services (Secretary) determined that a public health emergency (PHE) exists for the United States to aid the nation's health care community in responding to COVID–19 (hereafter referred to as the PHE for COVID–19). On March 11, 2020, the WHO publicly declared COVID–19 a pandemic. On March 13, 2020, the President of the United States declared the COVID–19 pandemic a national emergency. The January 31, 2020 determination that a PHE for COVID–19 exists and has existed since January 27, 2020, lasted for 90 days, and was renewed on April 21, 2020; July 23, 2020; October 2, 2020; and January 7, 2021. Pursuant to section 319 of the PHSA, the determination that a PHE continues to exist may be renewed at the end of each 90-day period.[1] Data from the Centers for Disease Control and Prevention (CDC) and other sources have determined that some people are at higher risk of severe illness from COVID–19.[2]

Individuals residing in congregate settings, regardless of health or medical conditions, are at greater risk of acquiring infections, and many residents and clients of long-term care (LTC) facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs–IID) face higher risk of severe illness due to age, disability, or underlying health conditions. Nursing home residents are less than 1 percent of the American population, but have historically accounted for over one-third of all COVID–19 deaths.[3]

[1] *https://www.phe.gov/emergency/events/COVID19/Pages/2019-Public-Health-and-Medical-Emergency-Declarations-and-Waivers.aspx.*

[2] Centers for Disease Control and Prevention. (2020). People at Increased Risk. Retrieved from: *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html.*

[3] See The Long-Term Care COVID Tracker at *https://covidtracking.com/nursing-homes-long-term-care-facilities,* and the KFF State COVID–19 Data and Policy Actions at *https://www.kff.org/coronavirus-covid-19/issue-brief/state-covid-19-data-and-policy-actions/#longtermcare.* These data may understate the problem because some states do

A. COVID–19 in Congregate Living Settings

Since there is no single official definition of congregate living settings, also referred to as residential habilitation settings, for purposes of this discussion we describe them as shared residences of any size that provide services to clients and residents. People living and working in these living situations may have challenges with social distancing and other mitigation measures, like mask use and handwashing, that help to prevent the spread of SARS–CoV–2. Residents, clients, and staff typically may gather together closely for social, leisure, and recreational activities, shared dining, and/or use of shared equipment, such as kitchen appliances, laundry facilities, vestibules, stairwells, and elevators. Residents in some congregate living facilities may also receive care from day habilitation facilities such as adult day health centers. Some congregate living residents require close assistance and support from facility staff, which further reduces their ability to maintain physical distance. On March 2, 2021, CDC issued *Interim Considerations for Phased Implementation of COVID–19 Vaccination and Sub-Prioritization Among Recommended Populations,* which notes that increased rates of transmission have been observed in these settings, and that jurisdictions may choose to prioritize vaccination of persons living in congregate settings based on local, state, tribal, or territorial epidemiology. CDC further notes that congregate living facilities may choose to vaccinate residents and clients at the same time as staff, because of shared increased risk of disease.[4]

This rule establishes requirements for LTC facilities and ICFs–IID; however, we recognize that individuals in all congregate living settings may have had similar experiences and outcomes during the PHE as individuals living or staying in institutional settings. We acknowledge that many congregate living facilities may not fall into any single category or may be classified differently depending on the state in which they are located. We further note that some other congregate living settings, such as dormitories, prisons, and shelters for people experiencing homelessness, have also faced higher risks of disease transmission, and these settings are not within our scope of authority. CMS is seeking public comment on the feasibility of implementing vaccination policies for other Medicare/Medicaid participating shared residences in which one or more people reside such as but not limited to the following: Psychiatric residential treatment facilities (PRTFs), psychiatric hospitals, forensic hospitals, adult foster care homes (AFC homes), group homes, assisted living facilities (ALFs), supervised apartments, and inpatient hospice facilities.

We considered extending the requirements included in this rule to other congregate living settings for which we have regulatory authority, including inpatient psychiatric hospitals (which are subject to the majority of Hospital Conditions of Participation, including § 482.42, ''Infection Control'') and PRTFs, but have not included such requirements in this interim final rule because we believe it would not be feasible at this time. Individuals in psychiatric hospitals, for example, may only be in-patients for short periods, making appropriate provision of a two-dose vaccine series challenging, although a one dose vaccine product is also now authorized. Because we are not able to guarantee sufficient availability of single dose COVID–19 vaccines at this time, or in the near future, to meet the potential demands of facilities with relatively short stays, we are focusing on facilities that have longer term relationships with patients and are thus also able to administer all doses of and track multi-dose vaccines. PRTFs only serve children and youth under the age of 21 years, and there is not yet a COVID–19 vaccine authorized or licensed for people younger than the age of 16 years in the United States. We are seeking public comment on the feasibility of adding appropriate COVID–19 vaccination requirements for residents, clients, and staff of all congregate living facilities where CMS has regulatory authority and pays for some portion of the care and services provided. Specifically, we are interested in comments on potential barriers facilities may face in meeting the requirements, such as staffing issues or characteristics of the resident or client population, and potential unintended consequences. We welcome suggestions on how the regulations should be revised to ensure that congregate living within our regulatory authority are able to reduce the spread of SARS–CoV–2 infections.

While congregate living settings are also often part of a state's and home and community-based services (HCBS) infrastructure. HCBS is an umbrella term for long term services and supports that are provided to people in their own homes or communities rather than institutions or other isolated settings. These programs serve a diverse population, including people with intellectual or developmental disabilities, physical disabilities, mental illness, and HIV/AIDS. Shared living arrangements within, and the sharing of staff across these and other settings can lead to increased risk of COVID–19 outbreaks. In addition, individuals living in these settings often have multiple chronic conditions that can increase the risk of severe disease and complicate treatment of, and recovery from, COVID–19. This makes the vaccination of clients and staff in these congregate living settings a critical component of a jurisdiction's vaccine implementation plan.

In an effort to facilitate a comprehensive vaccine administration strategy, we encourage providers who manage Medicare and/or Medicaid participating congregate living settings (such as psychiatric hospitals or PRTFs) or settings in which Medicaid-funded HCBSs are provided (ALFs, group homes, shared living/host home settings, supported living settings, and others) to voluntarily engage in the provision of the culturally and linguistically appropriate and accessible education and vaccine-offering activities described in this IFC. Vaccine availability may vary based on location, and vaccination and medical staff authorized to administer the vaccination may not be readily available onsite at many congregate living or residential care settings. Therefore, facilities should consult state Medicaid agencies and state and local health departments to understand the range of options for how vaccine provision can be made available to residents, clients, and staff. In addition, we encourage state Medicaid agencies, in partnership with public health agencies, to collaborate with congregate living settings to ensure their involvement in vaccine distribution strategies, and to facilitate vaccination of beneficiaries and staff as efficiently as possible. Lastly, we request public comment on challenges congregate living settings might encounter in complying with these IFC provisions, including in reporting vaccine information to CDC's National Healthcare Safety Network (NHSN).

We acknowledge the diversity and complexity of the needs of congregate living facilities. We understand that factors such as coordination of care with day habilitation sites, adult day health providers, hospice providers, and other entities, and also high rates of staff turnover may impede the implementation of a COVID–19

not count as nursing home deaths persons infected in nursing homes but transferred to hospitals and recorded as hospital deaths.

[4] *https://www.cdc.gov/vaccines/covid-19/phased-implementation.html#congregate-living-settings.*

vaccination program. To enhance our future efforts to support reasonable and effective COVID–19 vaccination programs in congregate living facilities, we seek public comment on a number of issues, including the following:

- Are there state or local vaccine policies, for COVID–19 vaccines or otherwise, already in place for congregate living facilities and related agencies, such as adult day health programs, either in the licensing or certification requirements or elsewhere? How have they been helpful to your facility or program?
- Does your program or facility have vaccine policies? How are they structured and what challenges have you faced with regard to implementation? Do policies include residents, clients and staff?
- If a vaccine policy applied to both shared living and day programs for adult day health or day habilitation, for example, who or what entity should have the responsibility for ensuring that all residents and staff have access to COVID–19 vaccination? Is there existing or capacity for case management for individuals engaging with both residential care and programs that occur outside the residential setting?
- What barriers exist to the implementation of a COVID–19 vaccination policy for residents and staff of congregate living facilities?
- How can equitable access to COVID–19 vaccine be ensured for residents and clients of congregate living facilities and related agencies?
- Are congregate living facilities currently facing challenges in tracking staff vaccination status? If so, explain.
- Has your State or county included residential and adult day health or day habilitation staff on the vaccine-eligible list as health care providers? What other impediments do staff face in getting access to vaccines?

Where such data are available, we are requesting respondents include data indicating:

- The rate of admission to congregate living facilities.
- The average length of stay for residents of congregate living facilities.
- The variety and prevalence of comorbidities in individuals served that may increase their risk of severe illness from COVID–19.
- The rate of employee sharing between congregate living facilities and the rate of employee turnover.

We acknowledge the lengths that congregate living and HCBS providers have gone to keep their residents, clients, and staff as safe as possible during the COVID–19 PHE, and request their input on ways that CMS and HHS can further support safety and reduce the risk of infection moving forward. This interim final rule with comment is one step in the broad effort to support those individuals at higher risk, in part because of living or working arrangements. Comments from congregate living providers, advocacy groups, professional organizations, HCBS providers (including day habilitation and adult day health providers), residents, clients, staff, family members, paid and unpaid caregivers, and other stakeholders will help inform future CMS actions.

B. ICFs–IID and COVID–19

ICFs–IID, residential facilities that provide services for people with disabilities, vary in size. In such settings, several factors may facilitate the introduction and spread of SARS–CoV–2, the virus that causes COVID–19. Staff working in these facilities often work across facility types (that is, nursing home, group home, different congregate settings within the employer's purview), and for different providers, which may contribute to disease transmission. Other factors impacting virus transmission in these settings might include: Clients who are employed outside the congregate living setting; clients who require close contact with staff or direct service providers; clients who have difficulty understanding information or practicing preventive measures; and clients in close contact with each other in shared living or working spaces. ICF–IID clients with certain underlying medical or psychiatric conditions may be at increased risk of serious illness from COVID–19.[5]

There are currently 5,768 Medicare- and/or Medicaid-certified ICFs–IID, and all 50 States have at least one ICF–IID. As of April 2021, 4,661 of the 5,770 are small (1 to 8 beds) in size, but there are 1,107 that are larger (14 or more beds) facilities. These facilities serve over 64,812 individuals with intellectual disabilities and other related conditions. ICFs–IIDs were originally conceived as large institutions, but caregivers and policymakers quickly recognized the potential benefits of greater community integration, spawning the growth in the early 1980s of community ICFs–IID with between four and 15 beds.[6] The number of individuals residing in large public ICFs–IID has decreased steadily over time (from 55,000 total residents in 1997 to approximately 16,000 as of April 2021). Many states have either closed a significant number of these facilities completely or downsized them through ''rebalancing'' efforts,[7] and the impetus of the Supreme Court's *Olmstead* decision.[8] Many ICF–IID clients have multiple chronic conditions and psychiatric conditions in addition to their intellectual disability, which can impact a client's understanding or acceptance of the need for vaccination. All must financially qualify for Medicaid assistance. While national data about ICF–IID clients is limited, we take an example from Florida, almost one quarter (23 percent) require 24-hour nursing services and a medical care plan in addition to their services plans.[9] Data from a single state is not nationally representative and thus we are unable to generalize, but it is illustrative and consistent with other states' trends. These co-occurring conditions may increase the risks of infectious diseases for clients of ICFs–IID above the risk levels experienced by the general population. Clients and residents often live in close quarters. Some may not understand the dangers of the virus, or be able to independently comply with mitigation measures. Those who need help with activities of daily living cannot maintain their distance from staff and caregivers. During the PHE, some facilities have struggled to retain staff and, as noted above, some staff working in these facilities may also have more than one job that puts them at higher risk.[10] Currently, the Conditions of Participation: ''Health Care Services'' at § 483.460(a)(3), require ICFs–IID to provide or obtain preventive and general medical care as well as annual physical examinations of each client that at a minimum include the following: Evaluation of vision and hearing; immunizations; routine screening laboratory examinations as determined necessary by the physician, special studies when needed; and tuberculosis control, appropriate to the facility's population. While the existing requirements should ensure that ICFs–IID provide clients with a COVID–19 vaccine, we note that it does not address vaccine education. Further, we believe that the unprecedented risks associated with the COVID–19 PHE warrant direct attention. ICFs–IID have not historically been required to participate in national reporting programs to the extent that

[5] *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html.*

[6] *https://aspe.hhs.gov/system/files/pdf/76956/MFIS.pdf.*

[7] *https://www.medicaid.gov/sites/default/files/2019-12/mfp-rtc.pdf.*

[8] *https://www.ada.gov/olmstead/S.*

[9] *http://www.floridaarf.org/assets/Files/ICF-IID%20Info%20Center/ICFHandoutonwebsite2-14.pdf.*

[10] *https://www.medicaid.gov/medicaid/long-term-services-supports/workforce-initiative/index.html.*

other health care facilities have. Despite the limited data available regarding COVID–19 cases or outbreak in ICFs–IID, we recognize the unique concerns for these facilities and their clients and staff. We note that CDC has established COVID–19 infection, prevention, and control guidance specific to group homes for individuals with disabilities, as noted earlier, recently released an updated guidance on vaccination and sub-prioritization that discusses this group.[11]

CMS and other Federal agencies took many actions and exercised regulatory flexibilities to help health care providers contain the spread of SARS–CoV–2. When the President declares a national emergency under the National Emergencies Act or an emergency or disaster under the Stafford Act, CMS is empowered to take proactive steps by waiving certain CMS regulations, as authorized under section 1135 of the Social Security Act (''1135 waivers''). CMS may also waive requirements set out under section 1812(f) of the Social Security Act (the Act) applicable to skilled nursing facilities (SNFs) under Medicare (''1812(f) waivers''). The 1135 waivers and 1812(f) waivers allowed us to rapidly expand efforts to help control the spread of SARS–CoV–2.

Currently, CMS has waived the following regulations for ICF–IIDs, with a retroactive effective date of March 1, 2020, and continuing through the end of the public health emergency declaration and any extensions, unless they are terminated earlier. CMS has waived the requirements at § 483.430(c)(4), which requires the facility to provide sufficient Direct Support Staff (DSS) so that Direct Care Staff (DCS) are not required to perform support services that interfere with direct client care. We also waived the requirements at § 483.420(a)(11) which requires clients have the opportunity to participate in social, religious, and community group activities. Finally, we also waived, in part, the requirements at § 483.430(e)(1) related to routine staff training programs unrelated to the public health emergency. CMS has not waived § 483.430(e)(2) through (4), which requires focusing on the clients' developmental, behavioral, and health needs and being able to demonstrate skills related to interventions for challenging behaviors and implementing individual plans.

CMS recognizes that during the public health emergency ''active treatment'' may need to be modified. The requirements at § 483.440(a)(1) require that each client receive a continuous active treatment program, which includes consistent implementation of a program of specialized and generic training, treatment, health services and related services. CMS is currently waiving those components of beneficiaries' active treatment programs and training that would violate current state and local requirements for social distancing, staying at home, and traveling for essential services only.

C. LTC Facilities and COVID–19

Long-term care facilities, a category that includes Medicare SNFs and Medicaid nursing facilities (NFs), must meet the consolidated Medicare and Medicaid requirements for participation (requirements) for LTC facilities (42 CFR part 483, subpart B) that were first published in the **Federal Register** on February 2, 1989 (54 FR 5316). These regulations have been revised and added to since that time, principally as a result of legislation or a need to address specific issues. The requirements were comprehensively reviewed and updated in October 2016 (81 FR 68688), including a comprehensive update to the requirements for infection prevention and control.

Since the onset of the PHE, we have revised the requirements for LTC facilities through two interim final rules with comment periods (IFCs) to establish reporting and testing requirements specific to the mitigation of the current pandemic. The first IFC was the ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' interim final rule with comment, which appeared in the May 8, 2020 **Federal Register** (85 FR 27550) with an effective date of May 8, 2020 (hereafter referred to as the ''May 8th COVID–19 IFC'').[12] The May 8th COVID–19 IFC established requirements for LTC facilities to report information related to COVID–19 cases among facility residents and staff. We received 299 public comments in response to the May 8th COVID–19 IFC. About 161, or over one-half of those comments, addressed the requirement for COVID–19 reporting for LTC facilities set forth at § 483.80(g). The second IFC was the ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment, which appeared in the September 2, 2020 **Federal Register** (85 FR 54820) with an effective date of September 2, 2020 (hereafter referred to as the ''September 2nd COVID–19 IFC'').[13] The September 2nd COVID–19 IFC strengthened CMS' ability to enforce compliance with LTC reporting requirements and established a new requirement for LTC facilities to test facility residents and staff for COVID–19. We received 171 public comments in response to the September 2nd COVID–19 IFC, of which 113 addressed the requirement for COVID–19 testing of LTC facility residents and staff set forth at § 483.80(h).

Health care inequities faced by the general population, discussed further in Section I.D. of this rule, are also seen within LTC facilities. Despite the increased use of nursing homes by minority residents, nursing home care remains highly segregated. Compared to Whites, racial/ethnic minorities tend to be cared for in facilities with limited clinical and financial resources, low nurse staffing levels, and a relatively high number of care deficiency citations.[14] Nursing homes with relatively high shares of Black or Hispanic residents were more likely to report at least one COVID–19 death than nursing homes with lower shares of Black or Hispanic residents.[15]

D. Current COVID–19 Vaccination Activities in LTC Facilities and ICFs–IID

Because of the expedient development of COVID–19 vaccines and their authorization for emergency use by the U.S. Food and Drug Administration (FDA), the requirements for LTC facilities and Conditions of Participation (CoPs) for ICFs–IID do not currently address issues of resident and staff vaccination education, or reporting COVID–19 vaccinations or therapeutic treatments to CDC. Nonetheless, many facilities across the country are educating staff, residents, and resident representatives; participating in vaccine distribution programs; and voluntarily reporting vaccine administration. However, participation in these efforts is not universal and we are concerned that many groups at higher risk of infection, specifically residents and clients of LTC facilities and ICFs–IID,

[11] *https://www.cdc.gov/coronavirus/2019-ncov/community/group-homes.html.*

[12] *https://www.federalregister.gov/documents/search?conditions%5Bterm%5D=85FR27550#.*

[13] *https://www.federalregister.gov/documents/search?conditions%5Bterm%5D=85FR54820#.*

[14] *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.0094.*

[15] *https://www.kff.org/070b9a9/.*

are not able to access COVID–19 vaccination. While all nursing homes across the U.S. (whether or not certified as a Medicare or Medicaid provider) were invited to participate in the COVID–19 vaccination Pharmacy Partnerships (discussed further in section II.A.1. of this rule), internal CDC data show that approximately 2,500 Medicare or Medicaid-certified LTC facilities (approximately 16 percent) did not participate in the Pharmacy Partnership program.

Given the congregate living models of LTC facilities and ICFs–IID, and the higher risk nature of their residents and clients due to age, comorbidities, and disabilities, people living and working in these facilities are at high risk of COVID–19 outbreaks, with residents and clients seeing higher rates of incidence, morbidity, and mortality than the general population. Data submitted to CDC's NHSN and posted on *data.cms.gov* for the week ending April 11, 2021 shows cumulative totals of 647,754 LTC resident COVID–19 confirmed cases and 131,926 LTC resident COVID–19 confirmed deaths. Also, there have been at least 569,502 total LTC staff COVID–19 confirmed cases and 1,888 total LTC staff COVID–19 confirmed deaths, on a cumulative basis. While we do not currently have data regarding the incidence of COVID–19 cases in ICFs–IID, we believe that these facilities may have also experienced significant rates of infection and that these data are likely an underestimate. A FAIR Health study examined the relationship between preexisting comorbidities of COVID–19 and mortality in privately insured individuals as reported in a white paper, Risk Factors for COVID–19 Mortality among Privately Insured Patients: A Claims Data Analysis.[16] The paper states that there are several possible reasons for the high COVID–19 mortality risk in people with developmental disorders and intellectual disabilities. These include greater prevalence of comorbid chronic conditions. We seek information from the public regarding the epidemiologic burden of COVID–19 on ICFs–IIDs, reporting COVID–19 data by ICFs–IID, existing barriers to reporting, and ways to enhance and encourage voluntary reporting of COVID–19-related data to CDC's NHSN reporting module.

We also request comment on inequities in COVID–19 preventive care that may have been experienced by LTC facility residents and ICF–IID clients. This IFC aims to ensure that all LTC facility residents, ICF–IID clients, and the staff who care for them, are provided with ongoing access to vaccination against COVID–19. The accountable entities responsible for the care of residents and clients of LTC facilities and ICFs–IID must proactively pursue access to COVID–19 vaccination due to a unique set of challenges that generally prevent these residents and clients from independently accessing the vaccine. These challenges create potential disparities in vaccine access for those residing in LTC facilities and ICFs–IID. CDC has recommended states place LTC facility residents and health care personnel into Phase 1a.[17] Despite their inclusion in most states' tier 1 vaccine priority category, it is CMS's understanding that very few individuals who are residents of LTC facilities are likely able to independently schedule or travel to public offsite vaccination opportunities. People reside in LTC facilities and ICFs–IID because they need ongoing support for medical, cognitive, behavioral, and/or functional reasons. Because of these issues, they may be less capable of self-care, including arranging for preventive health care. Independent scheduling and traveling off-site may be especially challenging for people with low health literacy, intellectual and developmental disabilities, dementia including Alzheimer's disease, visual or hearing impairments, or severe physical disability. This situation is particularly concerning because people with intellectual or developmental disabilities are at a disproportionate risk of contracting COVID–19.[18]

Similarly, there are large subpopulations of Americans who experience inequities on a regular basis in accessing quality health care beyond COVID–19 vaccination. Certain groups experience health and health care inequity, such as racial and ethnic minorities; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; people with disabilities; people living in rural areas; and others.

The COVID–19 pandemic has exacerbated these health care inequities as the country faces a convergence of economic, health, and climate crises.[19] Historical patterns of inequity in health care may persist despite the emphasis of public health officials on the need for equitable access to and utilization of preventive measures. Inequities have persisted through the COVID–19 PHE, with racial and ethnic minorities continuing to have higher rates of infection and mortality.[20] Ensuring that all residents, clients, and staff of LTC facilities and ICFs–IID have access to COVID–19 vaccinations seeks to address some of those inequities and provide timely protection for these individuals.

Ensuring that all LTC facility residents, ICF–IID clients, and the staff who care for them are provided with ongoing opportunities to receive vaccination against COVID–19 is critical to ensuring that populations at higher risk of infection continue to be prioritized, and receive timely preventive care during the COVID–19 PHE. This rule establishes penalties for non-compliance, in order to require facilities to educate about and offer vaccination to residents and staff.

Based on the current rate of incidence of COVID–19 disease and deaths among LTC residents, we believe more action can be taken to help staff and residents avoid contracting SARS–CoV–2. LTC facility staff are also at risk of transmitting SARS–CoV–2 to residents, experiencing illness or death as a result of COVID–19 themselves, and transmitting it to their families, friends, unpaid caregivers and the general public. Asymptomatic people with SARS–CoV–2 may move in and out of the LTC facility and the community, putting residents and staff at risk of infection. Routine testing of LTC residents and staff, along with visitation restrictions, personal protective equipment (PPE) usage, social distancing, and vaccination for residents and staff are all part of CDC's Interim Infection Prevention and Control Recommendations to Prevent SARS–CoV–2 Spread in Nursing Homes.[21] COVID–19 vaccines are a crucial tool for slowing the spread of disease and death among both residents, staff, and the general public. Based on the Food and Drug Administration's (FDA) review, evaluation of the data, and their decision to authorize three vaccines for emergency use, we recognize that these vaccines meet FDA's standards for an emergency use authorization (EUA) for safety and effectiveness to prevent

[16] *https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/Risk%20Factors%20for%20COVID-19%20Mortality%20among%20Privately%20Insured%20Patients%20-%20A%20Claims%20Data%20Analysis%20-%20A%20FAIR%20Health%20White%20Paper.pdf.*

[17] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations.html.*

[18] *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-developmental-disabilities.html.*

[19] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[20] *https://tcf.org/content/commentary/even-nursing-homes-covid-19-racial-disparities-persist/?agreed=1.*

[21] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html.*

COVID–19 disease and related serious outcomes, including hospitalization and death. The combination of vaccination, universal source control (wearing masks), social distancing, and hand-washing offers further protection from COVID–19.[22]

Similar to LTC facilities, due to the recent development and authorization of COVID–19 vaccines, the conditions of participation for ICF–IIDs do not currently address issues of client and staff vaccine education. Many CMS-certified ICFs–IID across the country are educating staff, clients, and client representatives, and attempting to participate in vaccination programs. However, participation in these efforts is not universal, and we are concerned that many individuals are not receiving these important preventive care services.

E. COVID–19 PHE and Vaccine Development

Ensuring that LTC residents, ICF–IID clients, and staff have the opportunity to receive COVID–19 vaccinations will help save lives and prevent serious illness and death. On December 1, 2020, the Advisory Committee in Immunization Practices (ACIP) met and provided recommendations; CDC adopted ACIP's recommendation: That health care personnel and long-term care facility residents be offered COVID–19 vaccination first (Phase 1a).[23]

All COVID–19 vaccines currently authorized for use in the United States were tested in clinical trials involving tens of thousands of people and met FDA's standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization. The clinical trials included participants of different races, ethnicities, and ages, including adults over the age of 65.[24] The most common side effects following vaccination are dependent on the specific vaccine that an individual receives, but the most common may include pain at the injection site, tiredness, headache, muscle pain, nausea, vomiting, fever, and chills.[25] After a review of all available information, ACIP and CDC have determined the lifesaving benefits of COVID–19 vaccination outweigh the risks or possible side effects.[26]

The COVID–19 vaccines currently authorized for use in the United States require either a single dose or a series of two doses given three to four weeks apart. Every person who receives a COVID–19 vaccine receives a vaccination record card noting which vaccine and the dose received. Vaccine materials specific to each vaccine are located on CDC and FDA websites. CDC has posted a LTC facility toolkit ''Preparing for COVID–19 Vaccination at your Facility'' at *https://www.cdc.gov/vaccines/covid-19/toolkits/long-term-care/.* This toolkit provides LTC administrators and clinical leadership with information and resources to help build vaccine confidence among residents, clients, and staff. CDC has also posted an ICF–IID toolkit ''Toolkit for people with Disabilities'' at *https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/people-with-disabilities.html. This toolkit provides* guidance and tools to help people with disabilities and paid and unpaid caregivers make decisions, help protect their health, and communicate with their communities.

While we are not requiring participation, we encourage individual residents, clients, and staff who use smartphones to use CDC's new smartphone-based tool called v-safe After Vaccination Health Checker (v-safe) to self-report on one's health after receiving a COVID–19 vaccine. V-safe is a new program that differs from the Vaccine Adverse Event Reporting System (VAERS), which we discuss in the section I.F. of this rule. Individuals may report adverse reactions to a COVID–19 vaccine to either program. Enrollment in v-safe allows individuals to directly report to CDC any problems or adverse reactions after receiving the vaccine. When an individual receives the vaccine, they should also receive a v-safe information sheet telling them how to enroll in v-safe. Individuals who enroll will receive regular text messages directing them to surveys where they can report any problems or adverse reactions after receiving a COVID–19 vaccine, as well as receive reminders for a second dose if applicable.[27] We note again that participation in v-safe is not mandatory, and further that individual participation is not traced to or shared with specific health care providers.

F. FDA & Emergency Use Authorization (EUA) of COVID–19 Vaccines

The FDA provides scientific and regulatory advice to vaccine developers and undertakes a rigorous evaluation of the scientific information through all phases of clinical trials; such evaluation continues after a vaccine has been licensed by FDA or authorized for emergency use.

CMS recognizes the gravity of the current public health emergency and the importance of facilitating availability of vaccines to prevent COVID–19. An EUA (authorized under section 564 of the Federal Food, Drug, and Cosmetic Act) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID–19 pandemic. The FDA may authorize certain unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.[28]

VAERS is a safety and monitoring system that can be used by anyone to report adverse events with vaccines. While the COVID–19 vaccines are being used under an EUA, vaccination providers, manufacturers, and EUA sponsors must, in accordance with the National Childhood Vaccine Injury Act (NCVIA) of 1986 (42 U.S.C. 300aa–1 to 300aa–34), report select adverse events to VAERS (that is, serious adverse events, cases of multisystem inflammatory syndrome (MIS), and COVID–19 cases that result in hospitalization or death).[29] Providers also must adhere to any revised safety reporting requirements. FDA's EUA website includes letters of authorization and fact sheets and these should be checked for any updates that may occur. Additional adverse events following vaccination may be reported to VAERS. Adverse events will also be monitored through electronic health record- and claims-based systems (that is, CDC's Vaccine Safety Datalink and Biologicals Effectiveness and Safety (BEST)). On December 11, 2020, the U.S. Food and Drug Administration issued the first

[22] *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.*

[23] *https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm.*

[24] *https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-diversity-within-covid-19-vaccine-clinical-trials-key-questions-and-answers/.*

[25] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html.*

[26] See Centers for Disease Control and Prevention. Benefits of Getting a COVID–19 Vaccine. *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html.* Updated January 5, 2021. Accessed January 14, 2021.

[27] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html.*

[28] *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

[29] Department of Health and Human Services. VAERS—Vaccine Adverse Event Reporting System. Accessed at *https://vaers.hhs.gov/.* Accessed on January 26, 2021.

EUA for a vaccine for the prevention of coronavirus disease 2019 (COVID–19) caused by severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) in individuals 16 years of age and older. The EUA allows the Pfizer-BioNTech COVID–19 vaccine to be distributed in the U.S. FDA has now issued EUAs for three vaccines for the prevention of COVID–19, to Pfizer (December 11, 2020) (16 years of age and older), Moderna (December 18, 2020) (18 years of age and older), and Johnson & Johnson's Janssen (February 27, 2021) (18 years of age and older). Fact sheets for healthcare providers administering vaccine are available for each vaccine product from theFDA.[30]

FDA is closely monitoring the safety of the COVID–19 vaccines authorized for emergency use. The vaccination provider is responsible for mandatory reporting to VAERS of certain adverse events as listed on the Health Care Provider Fact Sheet. The requirements for LTC facilities and ICFs–IID established by this IFC can be met by offering current and future COVID–19 vaccines authorized by FDA under EUA, or any COVID–19 vaccines licensed by FDA, as well as any COVID–19 vaccine boosters if authorized or licensed. We note that at this time, some LTC facility residents and ICF–IID clients may not be eligible to receive vaccination due to age (that is, they are younger than 16), but we anticipate that they may become eligible for vaccination if authorized use of COVID–19 vaccines is expanded in the future.

II. Provisions of the Interim Final Rule

In order to help protect LTC residents and ICF–IID clients from COVID–19, each facility must have a vaccination program that meets the educational and information needs of each resident, resident representative, client, parent (if the client is a minor) or legal guardian, and staff member. The program should provide COVID–19 vaccines, when available, to all residents and staff who choose to receive them. Consistent vaccination reporting by LTC facilities via the NHSN will help to identify LTC facilities that have potential issues with vaccine confidence or slow uptake among either residents or staff or both. The NHSN is the Nation's most widely used health care-associated infection (HAI) tracking system. It furnishes states, facilities, regions, and the Government with data regarding problem areas and measures of progress. CDC and CMS use information from NHSN to support COVID–19 vaccination programs by focusing on groups or locations that would benefit from additional resources and strategies that promote vaccine uptake. CMS Federal surveyors and state agency surveyors will use the vaccination data in conjunction with the reported data that includes COVID–19 cases, resident deaths, staff shortages, PPE supplies and testing. This combination of reported data is used by surveyors to determine individual facilities that need to have focused infection control surveys. Facilities having difficulty with vaccine acceptance can be identified through examining trends in NHSN data; and the Quality Improvement Organizations (QIOs), groups of health quality experts, clinicians, and consumers organized to improve the quality of care delivered to people with Medicare, can provide assistance to increase vaccine acceptance. Specifically, QIOs may provide assistance to LTC facilities by targeting small, low performing, and rural nursing homes most in need of assistance, and those that have low COVID–19 vaccination rates; disseminating accurate information related to access to COVID–19 vaccines to facilities; educating residents and staff on the benefits of COVID–19 vaccination; understanding nursing home leadership perspectives and assist them in developing a plan to increase COVID–19 vaccination rates among residents and staff; and assisting providers with reporting vaccinations accurately.

As discussed in detail below, we are revising the LTC facility requirements to specify that facilities must educate all residents and staff about COVID–19 vaccines, offer vaccination to all residents and staff, and report certain data regarding vaccination and therapeutic treatments to CDC via NHSN. Likewise, we are revising the ICF–IID Conditions of Participation to require that facilities must educate all clients and staff about COVID–19 vaccines and offer vaccination to all clients and staff. Reporting is not required for the ICFs–IID, however we strongly encourage voluntary reporting.

Immunization education, delivery, and reporting for influenza and pneumococcal vaccines are already a routine part of LTC facilities' infection control and prevention plans. We also require LTC facilities to offer education on influenza and pneumococcal vaccines and to give the resident or the resident representative the opportunity to accept or refuse vaccine.[31] LTC facilities must document a resident's uptake or refusal of influenza and pneumococcal immunization in the resident's medical record and report through a different electronic submission system, the Minimum Data Set (MDS). In order to standardize COVID–19 infection control and prevention in LTC facilities, we are issuing these requirements for facilities to provide COVID–19 vaccine education, offer COVID–19 vaccination, and report COVID–19 vaccinations for LTC facility residents and staff.

We require ICFs–IID to provide or obtain health care services for clients, including immunization, using as a guide the recommendations of the CDC Advisory Committee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics.[32] While the ICF–IID CoPs do not currently address specific vaccinations, the unprecedented risk of COVID–19 illness demands specific attention to protect clients. As discussed in section B.3. of this IFC, we are not issuing COVID–19 vaccination reporting requirements for ICFs–IID at this time due to current low rates of participation in NHSN by ICFs–IID and the delays that would be incurred by equipment acquisition (in some facilities) and NHSN enrollment, verification, and training.

A. Long-Term Care Facilities

1. Offer and Provide Vaccine to LTC Residents and Staff

With this IFC, we are amending the requirements at § 483.80 to add a new paragraph (d)(3). We require at new § 483.80(d)(3)(i) that LTC facilities develop and implement policies and procedures to ensure that they offer residents and staff vaccination against COVID–19 when vaccine supplies are available. We note that we are permitting but not requiring LTC facilities to provide the vaccine directly. They may also provide it indirectly, such as through arrangement with a pharmacy partner or local health department. Implementation of COVID–19 vaccine education and vaccination programs in LTC facilities will protect residents and staff, allowing for an expedited return to more normal routines, including timely preventive health care; family, caregiver, and community visitation; and group and individual activities. While we require that all residents and staff must be educated about the vaccine, we note that in situations, for example, where an individual has already received a

[30] *https://www.fda.gov/media/144637/download, https://www.fda.gov/media/144413/download, https://www.fda.gov/media/146304/download.*

[31] § 483.80(d).

[32] *https://pediatrics.aappublications.org/content/145/3/e20193995.*

COVID–19 vaccine or has a known medical contraindication (that is, an allergy to vaccine ingredients or previous severe reaction to a vaccine), the facility is not required to offer vaccination to that person. CDC has posted ''Interim Clinical Considerations for Use of COVID–19 Vaccines Currently Authorized in the United States'' describing these clinical situations.[33] CDC advice and guidance documents are periodically updated to reflect the latest information, and we cite this as an example, not as a regulatory requirement. At § 483.70(i)(1), in accordance with accepted professional standards and practices, the LTC facility must maintain medical records on each resident that are complete and accurately documented. In order to maintain current information, refusal of a vaccine should be documented with the reason; if the resident received the vaccine(s) elsewhere that should also be documented.

CDC established the Pharmacy Partnership for Long-term Care Program (Pharmacy Partnership), a national distribution initiative that provides end-to-end management of the COVID–19 vaccination process, including cold chain management, on-site vaccinations, and fulfillment of certain reporting requirements, to facilitate safer vaccination of the LTC facility population (residents and staff), while reducing burden on LTC facilities and jurisdictional health departments.[34] Most LTC facility staff who had not received their COVID–19 vaccine elsewhere, or needed to complete a vaccine series, were also vaccinated as part of the program. At the time of publication, we do not have data on the Partnership accomplishments in vaccinating residents or staff, but as discussed in the Regulatory Impact Analysis (RIA) section of this rule, there is extensive turnover in both groups, establishing the need for ongoing vaccination policies and programs.

The Pharmacy Partnership is currently facilitating safe vaccination of some LTC facility residents and staff, while reducing the burden on LTC facilities. The facilities remain responsible for the care and services provided to their residents. CDC has expected pharmacy partners to provide program services on-site at participating facilities for approximately two months from the date of each facility's first vaccination clinic, concluding in all facilities by spring of 2021. Internal CDC data shows that 99 percent of participating SNFs had held their third (final) clinic as of March 15, 2021. As the Pharmacy Partnership for LTC program comes to an end, it is important to ensure facilities have policies and procedures to provide continued access to COVID–19 vaccine for new or unvaccinated residents and staff, groups that will each exceed in magnitude over the course of this year a number larger than those offered vaccination during the Partnership's tenure. The Federal Government has also launched the Federal Retail Pharmacy Program, a collaboration between the Federal Government, states, and territories, and 21 national pharmacy partners and independent pharmacy networks representing over 40,000 pharmacies nationwide, including LTC facility pharmacy locations. This collaboration is intended to enhance the opportunities for vaccine uptake in congregate living settings.

For residents and staff who opt to receive the vaccine, vaccination must be conducted in a safe and sanitary manner in accordance with § 483.80; and as required by the vaccine provider agreements, COVID–19 vaccination clinics must be conducted in a manner for safe delivery of vaccines during the COVID–19 pandemic.[35] All facilities must adhere to current CDC infection prevention and control (IPC) recommendations. Screening individuals for currently suspected or confirmed cases of COVID–19, previous allergic reactions, and administration of therapeutic treatments and services is important for determining whether these individuals are appropriate candidates for vaccination at any given time. According to current CDC guidelines, anyone infected with COVID–19 should wait until infection resolves and they have met the criteria for discontinuing isolation.[36] We note that indications and contraindications for COVID–19 vaccination are evolving, and LTC facility Medical Directors and Infection Preventionists (IPs) should be alert to any new or revised guidelines issued by CDC, FDA, vaccine manufacturers, or other expert stakeholders.

Staff at LTC facilities should follow the recommended IPC practices described on CDC's website for LTC facilities.[37] For example, the website currently has ''Long-Term Care Facility Toolkit: Preparing for COVID–19 in LTC facilities'' [38] and the ''Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID–19) Pandemic.'' [39] These recommendations, which emphasize close monitoring of residents of long-term care facilities for symptoms of COVID–19, universal source control, physical distancing, hand hygiene, and optimizing engineering controls, are intended to help protect staff and residents from exposure.

Administration of any vaccine includes appropriate monitoring of vaccine recipients for adverse reactions. CDC has information describing IPC considerations for residents of long-term care facilities with systemic signs and symptoms following COVID–19 vaccination. See ''Post-Vaccine Considerations for Residents,'' located at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html.* This information is also included on FDA fact sheets. Long-term care facilities must have strategies in place to appropriately evaluate and manage post-vaccination signs and symptoms of adverse events among their residents.

CDC advises that COVID–19 vaccination providers document vaccine administration in their medical records system within 24 hours of administration and report administration data as specified in their vaccine provider agreements and to applicable local vaccine tracking programs (that is, Immunization Information System) as soon as practicable and no later than 72 hours after administration. While LTC facility staff may not have personal medical records on file with the employing LTC facility, all staff COVID–19 vaccinations must be appropriately documented by the facility in a manner that enables the facility to report in accordance with this rule (that is, in a facility immunization record, personnel files, health information files, or other relevant document). Updates to CDC's COVID–19 Vaccination Program Provider Agreement Requirements can be located on CDC's website.[40]

[33] *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html*

[34] *https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html* and provide additional information on vaccination under this program: *https://covid.cdc.gov/covid-data-tracker/#vaccinations-ltc*

[35] *https://www.cdc.gov/vaccines/pandemic-guidance/index.html.*

[36] Interim Guidance on Duration of Isolation and Precautions for Adults with COVID–19 | CDC, *https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.*

[37] *https://www.cdc.gov/longtermcare/.*

[38] *https://www.cdc.gov/vaccines/covid-19/toolkits/long-term-care/.*

[39] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.*

[40] Centers for Disease Control and Prevention. CDC COVID–19 Vaccination Program Provider Requirements and Support. Accessed at *https://www.cdc.gov/vaccines/covid-19/vaccination-*

Continued

2. COVID–19 Disease and Vaccine Education

a. LTC Facility Staff

Given the new and emerging nature of COVID–19 disease, vaccines, and treatments, we recognize that education is critical. With this IFC, we are amending the requirements at § 483.80 to add new paragraph (d)(3)(ii) to require that LTC facility staff are educated about vaccination against COVID–19. LTC facility staff are integral to the function of LTC facilities and the health and well-being of residents. For the purposes of COVID–19 vaccine education, offering, and reporting, we consider LTC facility staff to be those individuals who work in the facility on a regular (that is, at least once a week) basis. We note that this includes those individuals who may not be physically in the LTC facility for a period of time due to illness, disability, or scheduled time off, but who are expected to return to work. We also note that this description of staff differs from that in § 483.80(h), established for the LTC facility COVID–19 testing requirements in the September 2nd, 2020 COVID–19 IFC. This rule's description of LTC facility staff is limited to individuals working in the facility on a regular (at least weekly) basis, while the definition set out at § 483.80(h) includes workers who come into the facility infrequently, such as a plumber who may come in only a few times per year. We considered applying the § 483.80(h) definition to the vaccination and reporting requirements in this rule, but public feedback tells us the definition in paragraph (h) was overbroad for these purposes. Stakeholders report that there are many LTC facility staff and individuals providing occasional services under arrangement, and that the requirements may be excessively burdensome for the facilities to apply the definition at paragraph (h) because it includes many individuals who have very limited, infrequent contact with facility staff and residents. Stakeholders also report that providing the required education and offering vaccination to these individuals who may only make unscheduled visits to the facility would be extremely burdensome. That said, the description in this rule—individuals who work in the facility on a regular (that is, at least once a week) basis—still includes many of the individuals included in paragraph (h). In addition to facility-employed personnel, many facilities have services provided on-site, on a regular basis by individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, or volunteers. Any of these individuals who provide services on-site at least weekly would be included in ''staff'' who must be educated and offered the vaccine as it becomes available. As established by this rule at § 483.80(d)(3), LTC facilities are not required to educate and offer vaccination to individuals who provide services less frequently, but they may choose to extend such efforts to them. We strongly encourage facilities, when the opportunity exists and resources allow, to provide vaccination to all individuals who provide services less frequently.

There are also individuals who may enter the facility for specific purposes and for a limited amount of time, such as delivery and repair personnel, or volunteers who may enter the LTC facility infrequently (less than once a week). We believe it would be overly burdensome to mandate that each LTC facility educate and offer the COVID–19 vaccine to all individuals who enter the facility. However, while facilities are not required to educate and offer vaccination to these individuals, they may choose to extend their education and offering efforts beyond those persons that we consider to be staff for purposes of this rulemaking. We do not intend to prohibit such extensions and encourage facilities to educate and offer vaccination to these individuals as reasonably feasible.

We recognize that facilities may choose to use a broader definition of ''staff.'' We note that CDC defines ''staff'' in the NHSN as: Ancillary service employees, nurse employees, aide, assistant and technician employees, therapist employees, physician and licensed independent practitioner employees and other health care providers. Categories are further broken down into environmental, laundry, maintenance, and dietary services; registered nurses and licensed practical/vocational nurses; certified nursing assistants, nurse aides, medication aides, and medication assistants; therapists (such as respiratory, occupational, physical, speech, and music therapist) and therapy assistants; physicians, residents, fellows, advanced practice nurses, and physician assistants; and persons not included in the employee categories listed, regardless of clinical responsibility or patient contact, including contract staff, students, and other non-employees.[41]

We are requiring that LTC facility staff (that is, individuals who work in the facility on a regular basis) be educated about the benefits and risks and potential side effects of the COVID–19 vaccine. Educating staff further about the development of the vaccine, how the vaccine works, and the particulars of the multi-dose vaccine series is encouraged but not required. Broader understanding of the vaccine will support the national effort to vaccinate against COVID–19. Staff should be instructed about the importance of vaccination for residents, their personal health, and community health. Better understanding the value of vaccination may allow staff to appropriately educate residents and residents' family members and unpaid caregivers about the benefits of accepting the vaccine. While most residents in LTC facilities are isolated from the broader community during the PHE, staff travel to and from the facility and the community, presenting risks of transmitting the virus to or from residents, family members, other caregivers, and the public.

We note that for LTC facilities that participated in the Federal Pharmacy Partnership for Long-Term Care Program, pharmacies worked directly with LTC facilities to ensure staff who received the vaccine also received an EUA fact sheet before vaccination. The EUA fact sheet explains the risks and possible side effects and benefits of the COVID–19 vaccine they are receiving and what to expect.

Staff education must cover the benefits of vaccination, which typically include reduced risk of COVID–19 illness and related serious COVID–19 outcomes, including hospitalization and death, the bolstered protection offered by completing a full series of multi-dose vaccines if used, and other benefits identified as research continues. Early data also suggests that vaccination offers reduced risk of inadvertently transmitting the virus to patients and other contacts.[42] Staff education must also address risks associated with vaccination, which should include potential side-effects of the vaccine, including common reactions such as aches or fever, and rare reactions such as anaphylaxis.[43] The low likelihood of severe side effects should be included in this education. If other benefits or risks or possible side-effects are identified in

provider-support.html. Accessed on January 26, 2021.

[41] *https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html.*

[42] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html.*

[43] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html.*

the future, whether through research, or authorization or licensing of new COVID–19 vaccines, those facts should be incorporated into education efforts. Staff should also be informed about ongoing opportunities for vaccination, if they miss a Pharmacy Partnership clinic, for example, or initially declined vaccination but later decide to accept the vaccine. In addition to ongoing education and informational updates for all staff members, we expect that new staff will receive appropriate education on COVID–19 vaccines.

CDC and FDA have developed a variety of clinical educational and training resources for health care professionals related to COVID–19 vaccines, and CMS recommends that nurses and other clinicians work with their LTC facility's Medical Director and, and use CDC and FDA resources as sources of information for their vaccination education initiatives. The LTC Facility Toolkit: Preparing for COVID–19 Vaccination at Your Facility has information and resources to build confidence among staff and residents.[44] The FDA provides materials for industry and other stakeholder specific to the EUA process and the vaccines.[45] Examples of educational and training topics include engaging residents in effective COVID–19 vaccine conversations, answering questions about consent for vaccine, common side effects, educating residents and staff about what to expect after vaccination, and the importance of maintaining infection prevention and control practices after vaccination. Each vaccine manufacturer is also developing educational and training resources for its individual vaccine. Building vaccine understanding broadly among staff, residents, and resident representatives, as well as dispelling vaccine misinformation and spreading information about successes in the program are critical to improving vaccine uptake rates, with potential for reducing vaccine hesitancy and the spread of misinformation.

The facility's vaccination policies and procedures must be part of the IPC program. Facilities can determine where they keep the documentation that demonstrates educational efforts and offering the vaccine to staff. Some examples of evidence of compliance may include sign in sheets, descriptions of materials used to educate, summary notes from all-staff question and answer sessions. There may be posters and flyers announcing appointments for vaccine clinic days or other opportunities to be vaccinated.

b. LTC Facility Residents and Resident Representatives

With this IFC, we are amending the requirements at § 483.80 to add a new paragraph (d)(3)(iii) to require that LTC facility residents or resident representatives are educated about vaccination against COVID–19. Explaining the risks and possible side effects and benefits of any treatments to a resident or their representative in a way that they can understand is the standard of care, and a patient right as specified at § 483.10(c)(5). In LTC facilities, consent or assent for vaccination should be obtained from residents and/or their representatives as appropriate and documented in the resident's medical record. The residents or their representatives have the right to decline the vaccine, based on the resident's rights requirement at § 483.10(c)(5) (regarding the resident's right to be informed of risks and benefits of proposed care). It is important to talk to residents and representatives to learn why they may be declining vaccination on their own behalf, or on behalf of the resident, and tailor any educational messages accordingly. Residents may not be forced or required to be vaccinated if the person or their representative declines.

Resident representatives must be included as a component of the LTC facility's vaccine education plan, as the resident representatives may be called upon for consent and/or may be asked to assist in promoting vaccine uptake of the resident, as appropriate. We note that for LTC facilities participating in the Federal Pharmacy Partnership for Long-term Care Program, pharmacies will work directly with LTC facilities to ensure residents who receive the vaccine also receive an EUA fact sheet before vaccination. The EUA fact sheet explains the risks or potential side effects and benefits of the COVID–19 vaccine they are receiving and what to expect.

In addition to the topics addressed above for education of LTC facility staff, education of residents and resident representatives should cover that, at this time while the U.S. Government is purchasing all COVID–19 vaccine in the United States for administration through the CDC COVID–19 Vaccination Program, all LTC facility residents are able to receive the vaccine without any copays or out-of-pocket costs. The provider agreements for the CDC COVID–19 Vaccination Program specifically prohibit charging out-of-pocket fees to the vaccine recipient. Medicare pays for the administration of the COVID–19 vaccine to beneficiaries, and other public and private insurance providers are required to cover it as well. To ensure broad access to a vaccine for America's Medicare beneficiaries, CMS published an Interim Final Rule with Comment Period (IFC) on November 6, 2020, that implemented section 3713 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act which required Medicare Part B to cover and pay for a COVID–19 vaccine and its administration without any cost-sharing (85 FR 71142, November 6, 2020). Any vaccine that receives Food and Drug Administration (FDA) authorization, through an EUA, or is licensed under a Biologics License Application (BLA), will be covered under Medicare as a preventive vaccine at no cost to beneficiaries. The November 6th IFC also implemented section 3203 of the CARES Act that ensure swift coverage of a COVID–19 vaccine by most private health insurance plans without cost sharing from both in and out-of-network providers during the course of the PHE.[46] The Provider Relief Fund Uninsured Program will also reimburse for administration of COVID–19 vaccine to individuals who are uninsured.[47]

Education for residents and representatives must also provide the opportunity for follow-up questions and be conducted in a manner that is reasonably understood by the resident and the representatives.

3. LTC Facility Reporting

With this IFC, we are amending the requirements at § 483.80(g) to require that LTC facilities report to NHSN, on a weekly basis, the COVID–19 vaccination status and related data elements of all residents and staff. The data to be reported each week will be cumulative, that is, data on all residents and staff, including total numbers and those who have received the vaccine, as well as additional data elements. In this way, the vaccination status of every LTC facility will be known on a weekly basis. Data on vaccine uptake will be important to understanding the impact of vaccination on SARS–CoV–2 infections and transmission in nursing

[44] *https://www.cdc.gov/vaccines/covid-19/toolkits/long-term-care/.*

[45] *https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19.*

[46] Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency (85 FR 54820).

[47] *https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html.*

homes.[48] This understanding, in turn, will help CDC make changes to guidance to better protect residents and staff in LTC facilities. In addition, LTC facilities must also report any COVID–19 therapeutics administered to residents. CDC has currently defined ''therapeutics'' for the purposes of the NHSN as a ''treatment, therapy, or drug'' and stated that monoclonal antibodies are examples of anti-SARS–CoV–2 antibody-based therapeutics used to help the immune system recognize and respond more effectively to the SARS-CoV–2 virus.

LTC administrators and clinical leadership are encouraged to track vaccination coverage in their facilities and adjust communication with residents and staff accordingly. Facilities reporting vaccinations to the NHSN Long-Term Care Facility Component [49] or Healthcare Personnel Safety Component are encouraged to use the COVID–19 Vaccination module to track aggregate vaccination coverage in their facility, which can help target education efforts, plan resource needs, and update visitation and cohorting policies (that is, grouping residents within the facility while waiting for COVID–19 test results or showing signs of illness) as indicated by evolving public health guidelines. NHSN data will allow CDC to determine the number and percentage of staff and residents in each facility who have received the COVID–19 vaccine.[50]

Our intent in mandating reporting of COVID–19 vaccines and therapeutics to NHSN is in part to monitor broader community vaccine uptake, but also to allow CDC to identify and alert CMS to facilities that may need additional support in regards to vaccine education and administration. These specific data collections replace and refine the current requirement, set out at § 483.80(g)(1)(viii), based on the opportunities presented by the development and authorization of COVID–19 vaccines and therapeutic treatments. If we identify a need to collect other specific data related to COVID–19, we will do this through appropriate rulemaking. The information reported to CDC in accordance with § 483.80(g) will be shared with CMS and we will retain and publicly report this information to support protecting the health and safety of residents, staff, and the general public, in accordance with sections 1819(d)(3)(B) and 1919(d)(3) of the Act.

Aggregate COVID–19 vaccination data collected as a result of this rulemaking will be made available to the public in the future. We note that until that time, individuals may request data per the Freedom of Information Act (FOIA) (5 U.S.C. 552), which provides that, upon request from any person, a Federal agency must release any agency record unless that record falls within one of the nine statutory exemptions and three exclusions (see *https://www.foia.gov/faq.html* for detailed information). Further, FOIA requires that agencies make available for public inspection copies of records, which because of the nature of their subject matter, have become or are likely to become the subject of subsequent requests for substantially the same information. We have received, and expect to continue to receive, COVID–19-related FOIA requests. Facility influenza vaccine data are available through CMS's Care Compare tool because these data are collected directly through the MDS, which feeds into the Care Compare tool. Data submitted through NHSN concerning COVID–19 testing and cases in LTC facilities is publicly posted on *data.cms.gov.*[51]

We are aware that COVID–19 vaccine information may be reported to local and state health departments, as well as by various pharmacy partners, and we believe direct submission of data by LTC facilities through NHSN will show actions and trends that can be addressed more efficiently on a national level. All state health departments and many local health departments already have direct access through NHSN to LTC facilities' COVID–19 data and are using the data for their own local response efforts. Thus, reporting in NHSN will, in many cases, serve the needs of state and local health departments. We request public comment on whether states are collecting COVID–19 vaccination data already, through other mechanisms.

National reporting through NHSN, which is limited to enrolled health care providers, will allow CDC to examine vaccination coverage compared with community infection rates, to determine visitation and other COVID–19 infection prevention and control guidelines, including cohorting. Currently, low rates of voluntary use of NHSN for vaccination reporting precludes accurate estimates of vaccine coverage. Regular and required reporting into the NHSN and familiarity with the NHSN process will also increase the future capacity of facilities to report if new pandemics or other threats arise in the future.

Pharmacy partners reported vaccination clinics they held in LTC facilities, and they have shared these data with CDC. Internal CDC data shows that 99 percent of participating SNFs had held their 3rd (final) clinic as of March 15, 2021. However, they have not continued to collect or report these data after their clinics concluded. Additionally, the pharmacy partners only collected numerator data (the number of residents and staff vaccinated), and not denominator data (the total number of residents and staff). Therefore, CDC cannot calculate the percentages of residents and staff vaccinated in each facility via the Federal Pharmacy Partnership data.

NHSN provides the long-term means to collect these data now that the Pharmacy Partnership has finished and will allow for calculation of percentages of residents and staff vaccinated in every facility. We anticipate that the additional reporting burden to LTC facilities will be minimal. All LTC facilities are already required, at § 483.80(g), to report certain COVID–19 case and outcomes data to NHSN every week, and the new vaccination reporting is in the same NHSN reporting system they currently use. Finally, health departments for states, the District of Columbia, and territories all have access to NHSN data for their jurisdictions and can use these data to inform their own response efforts. Facilities can determine where they keep the documentation that should be collected so that they can comply with the NHSN COVID–19 vaccination reporting requirements for staff.

Therapeutic treatments for COVID–19 administered to LTC residents, such as those in the form of monoclonal antibodies delivered intravenously, must now also be reported through NHSN in accordance with new § 483.80(g)(1)(ix) so that CDC can appropriately monitor their use. This reporting of therapeutics requirement is similar to the requirement that hospitals must report information about therapeutics (85 FR 85866). Data on the use of therapeutics will be critical to help support allocation efforts to ensure that nursing homes have access to supplies and services to meet their needs. This requirement and burden will be submitted to OMB under OMB control number 0938–1363.

[48] *https://www.cdc.gov/nhsn/pdfs/covid19/ltcf/57.158-toi-508.pdf.*

[49] Centers for Disease Control and Prevention—National Healthcare Safety Network. Surveillance for Weekly HCP & Resident COVID–19 Vaccination. Accessed at *https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html.* Accessed on January 26, 2021.

[50] *https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html.*

[51] *https://www.medicare.gov/care-compare/.*

B. Intermediate Care Facilities for Individuals With Intellectual Disabilities

1. Offer and Provision of Vaccine to ICF–IID Clients and Staff

With this IFC, we are redesignating the current § 483.460(a)(4) to § 483.460(a)(5) and adding a requirement at new § 483.460(a)(4)(i) to require that ICFs–IID offer clients and staff vaccination against COVID–19 when vaccine supplies are available. The vaccine may be offered and provided directly by the ICF–IID or indirectly, such as through a local health department, pharmacy, or doctor's office. Vaccines may be administered onsite or at other appropriate locations. Implementation of COVID–19 education and vaccination programs in ICFs–IID will help protect clients and staff, allowing an eventual return to more normal routines, including timely preventive health care; family, caregiver and community visitors; and group and individual activities. While we require that all clients and staff must be educated about the vaccine, we note that in situations where an individual has already received the vaccine or has a known medical contraindication (that is, an allergy to vaccine ingredients or previous severe reaction to a vaccine), the facility is not required to offer vaccination to that person.[52]

The client, parent (if the client is a minor), or legal guardian (collectively, ''representative'') has the right to refuse treatment based on the requirement at § 483.420(a)(2) that states the facility must ensure the rights of all clients. Therefore, the facility must inform each client and/or the representative regarding the client's medical condition, developmental and behavioral status, attendant risks of treatment, and the right to refuse treatment. Clients and their representatives (on behalf of the client) have the right to refuse vaccination.

For clients and staff who opt to receive the vaccine, vaccination must be conducted in a sanitary manner in accordance with CDC, FDA, § 483.410(b) of the ICF–IID CoPs, and manufacturer guidelines. As required by the provider agreements, COVID–19 vaccination clinics must be conducted in a manner for safe delivery of vaccines during the COVID–19 pandemic.[53] All facilities should adhere to current CDC IPC recommendations. Screening individuals for suspected or confirmed cases of COVID–19, previous allergic reactions, and administration of therapeutic treatments is important for determining whether they are appropriate candidates for vaccination at any given time. According to current CDC guidelines, anyone infected with COVID–19 should wait until infection resolves and they have met the criteria for discontinuing isolation.[54] We note that indications and contraindications for COVID–19 vaccination are evolving, and the director of nursing (DON) or nursing staff of the facility should be alert to any new or revised guidelines issued by CDC, FDA, vaccine manufacturers, and other expert stakeholders.

Staff at ICFs–IID should follow the recommended IPC practices described on CDC's website for ICFs–IID. For example, the website currently has documents entitled ''Guidance for Group Homes for Individuals with Disabilities'' and the ''Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID–19) Pandemic''.[55] [56] These recommendations, which emphasize close monitoring of clients of group homes for individuals with disabilities or ICFs–IID for symptoms of COVID–19, universal source control, physical distancing, use of masks, hand hygiene, and optimizing engineering controls, are intended to protect staff, residents, and visitors from exposure to SARS-CoV–2.

Administration of any vaccine includes appropriate monitoring of vaccine recipients for adverse reactions. For the COVID–19 vaccines, safety monitoring is also being conducted.[57] CDC has information describing IPC considerations for residents of ICF–IIDs with systemic signs and symptoms following COVID–19 vaccination. See ''Vaccine considerations for people with disabilities,'' located at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/disabilities.html*. Post-vaccine considerations are listed out for consideration by ICFs–IID clinical staff. ICFs–IID must have strategies in place to appropriately evaluate and manage immediate post-vaccination adverse reactions among any individuals who are vaccinated on site, and risks and potential side effects of vaccination on clients.

CDC advises that COVID–19 vaccination providers should document vaccine administration in their medical records within 24 hours of administration and report administration data as specified in their vaccine provider agreements and to applicable local vaccine tracking programs (that is, Immunization Information System). While an ICF–IID is unlikely to be a COVID–19 vaccination provider, all vaccinations should be appropriately documented. While ICF–IID staff may not have personal medical records with the ICF–IID, ICFs–IID participating in voluntary NHSN reporting should appropriately document staff vaccinations in a manner that enables the facility to report in accordance with NHSN guidelines (that is, in a facility immunization record, personnel files, health information files, or other relevant documentation).

2. COVID–19 Disease and Vaccine Education

a. ICF–IID Staff

Given the new and emerging qualities of COVID–19 disease, vaccines, and treatments we recognize that education of clients and staff is critical. With this IFC, we are amending the conditions of participation at new § 483.460(a)(4)(ii) to require that ICF–IID staff are educated about vaccination against COVID–19. ICF–IID staff are integral to the function of the ICFs–IID and the health and well-being of clients. For the purposes of COVID–19 vaccine education and offering, we consider ICF–IID staff to be those individuals who work in the facility on a regular (that is, at least once a week) basis. We note that this includes those individuals who may not be physically in the ICF–IID for a period of time due to illness, disability, or scheduled time off, but who are expected to return to work. In addition to facility-employed personnel, many facilities have services provided on-site, on a regular basis by individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, behaviorists, mental health professionals, and volunteers. These individuals would be included in ''staff'' who must be educated and offered the vaccine as available.

There are also individuals who may enter the facility for specific purposes and for a limited amount of time, such as delivery and repair personnel, or volunteers who may enter the ICF–IID

[52] *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/specific-groups/allergies.html.*

[53] *https://www.cdc.gov/vaccines/pandemic-guidance/index.html.*

[54] Interim Guidance on Duration of Isolation and Precautions for Adults with COVID–19 | CDC, *https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.*

[55] *https://www.cdc.gov/coronavirus/2019-ncov/community/group-homes.html.*

[56] *https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.*

[57] *https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/covid-19-vaccine-safety-surveillance.*

infrequently (meaning less than once weekly). We believe it would be overly burdensome to mandate that each ICF–IID educate and offer the COVID–19 vaccine to all individuals who enter the facility. However, while facilities are not required to educate and offer vaccination to these individuals, they may choose to extend their education and offering efforts beyond those persons that we consider to be ''staff'' for purposes of this rulemaking. We do not intend to prohibit such extensions and encourage facilities to educate and offer vaccination to these individuals as reasonably feasible.

We recognize that facilities may choose to use a broader definition of ''staff.'' We note that CDC categorizes staff in the NHSN as: Ancillary service employees, nurse employees, aides, assistant and technician employees, therapist employees, physician and licensed independent practitioner employees and other health care providers. Categories are further broken down into environmental, laundry, maintenance, and dietary services; registered nurses (RNs) and licensed practical/vocational nurses; certified nursing assistants, nurse aides, medication aides, and medication assistants; therapists (such as respiratory, occupational, physical, speech, and music therapists) and therapy assistants; physicians, residents, fellows, advanced practice nurses, and physician assistants; and persons not included in the employee categories listed, regardless of clinical responsibility or patient contact, including contract staff, students, and other non-employees.[58]

For purposes of the CMS requirements related to COVID–19 education and vaccination issued in this rule, we believe that the NHSN definition may be impractical. In addition to regularly employed personnel, many facilities have services provided directly to residents under contract, such as physical therapy, occupational therapy, behavior therapy, case management, and mental health services. There are also individuals who may enter the facility for specific purposes and for a limited amount of time, such as delivery personnel, plumbers, and other vendors. Even regular volunteers may enter the ICF–IID infrequently. We do not believe that mandating these requirements for every individual who enters the facility at any time is necessary to protect the clients and staff. In addition, we believe it would be overly burdensome for the ICF–IID to educate and offer the COVID–19 vaccine to all individuals who enter the facility. Staff and resources are limited in ICFs–IID, and therefore staff may not be available to educate and offer the vaccine to every individual that enters.

We are requiring that ICF–IID staff (that is, individuals who are eligible to work in the facility on a routine, or at least once weekly, basis) be educated about the benefits and risks and potential side effects of the COVID–19 vaccine. Educating staff further about the development of the vaccine, how the vaccine works, and the particulars of multi-dose vaccine series is encouraged but not required. Broader understanding of the vaccine will support the national effort to vaccinate against COVID–19. Staff should be educated to help them understand the importance of vaccination for helping to safeguard clients, personal health, and broader community health. Better understanding of the value and safety of the vaccines will allow staff to appropriately educate clients and representatives about the benefits of accepting the vaccine.

Staff education must cover the benefits and risks or possible side effects of vaccination, which typically include reduced risk of COVID–19 illness, and related serious COVID outcomes, including hospitalization and death, the bolstered protection offered by completing a full series of multi-dose vaccines (if used), and other benefits identified as research and immunization continues. Staff education must also address risks associated with vaccination, which should include potential side-effects of the vaccine, including common reactions such as aches or fever, and rare reactions such as anaphylaxis. The low likelihood of severe side effects should be included in this education. If other benefits, risks, or side-effects are identified in the future, whether through research, or authorization or licensing of new COVID–19 vaccine products, those facts should be incorporated into education efforts. Staff should also be informed about ongoing opportunities for vaccination. Staff should be provided education on culturally appropriate ways to educate and share information with clients to prevent misinformation, confusion, or loss of credibility. In addition to ongoing education and informational updates for all staff members, we expect that new staff will be screened to determine vaccination status, and potential need for appropriate education on COVID–19 vaccines during their onboarding or orientation. CDC and FDA have developed a variety of clinical educational and training resources for health care professionals related to COVID–19 vaccines, and CMS recommends that nurses and other clinicians work with their ICF–IID's Medical Director and use CDC resources as the source of information for their vaccination education initiatives. Each manufacturer is also developing educational and training resources for its individual vaccine candidate. Building vaccine understanding broadly among staff, clients, and parent (if the client is a minor), or legal guardian or representative, as well as dispelling vaccine misinformation, are critical to vaccine uptake rates.

The facility vaccination policies and procedures must be developed as part of the COVID–19 immunization requirements at § 483.460(a)(4). Facilities can determine where they keep the documentation that demonstrates educational efforts and offering the vaccine to staff. Some examples of evidence of compliance may include sign in sheets, descriptions of materials used to educate, and summary notes from all-staff question and answer sessions. There may be posters and flyers announcing appointments for vaccine clinic days or other vaccination opportunities.

b. ICF–IID Clients

New § 483.460(a)(4)(iii) requires that ICF–IID clients, or their representatives are educated about vaccination against COVID–19. Explaining the risks and benefits of any treatments to a client or representative in a way that they understand is the standard of care. In ICFs–IID, consent or assent for vaccination should be obtained from clients or representatives and documented in the client's medical record. It is important to talk to clients and representatives to learn why they may be declining vaccination and tailor educational messages accordingly, that is, by addressing specific questions or concerns.

Clients of ICFs–IID and their representatives must be offered education about vaccine immunization development, administration, and evaluation. Representatives must be included as a component of the ICF–IID's vaccine education plan as the representatives may be called upon for consent and/or may be asked to assist in encouraging vaccine uptake by the client.

In addition to the topics addressed above for education of ICF–IID staff, education of clients and representatives should cover the fact that, at this time while the U.S. Government is purchasing all COVID–19 vaccine in the

[58] *https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html.*

United States for administration through the CDC COVID–19 Vaccination Program, all ICF–IID clients are able to receive the vaccine without any copays or out-of-pocket costs. Currently Medicaid pays for the administration of the COVID–19 vaccine to beneficiaries, and other public and private insurance providers are required to cover it as well.

Education for clients and representatives must also provide the opportunity for follow up questions, and be conducted in a manner that is reasonably understood by the clients and representatives. Information should be made available in accessible formats as appropriate for a facility's population. That is, educational materials and delivery must meet relevant standards in Section 504 of the Rehabilitation Act, which may include making such material available in large print, Braille, and American Sign Language, and using close captioning, audio descriptions, and plain language for people with vision, hearing, cognitive, and learning disabilities.

3. ICF–IID Voluntary Reporting

While there would be great value in collecting more data about COVID–19 incidence and vaccinations in ICFs–IID, we are not mandating such data submission at this time. Currently there are only approximately 80 ICFs–IID participating in the NHSN or any other formal reporting program, although there are opportunities for ICFs–IID to enroll. Requiring all ICFs–IID to report to NHSN would create a new field of administrative burden for ICFs–IID, potentially requiring new equipment, administrative staff, and training. Further, reporting through NHSN would require time, likely several weeks to months, for the facilities not yet participating in NHSN to complete enrollment with CDC and appropriately train those staff who would be responsible for data submission, effectively making compliance within the effective date of this IFC nearly impossible. Based on the information we have received from stakeholders, we do not believe that ICFs–IID are administering therapeutics at this time. We encourage voluntary reporting as facilities are able to do so.

C. Enforcement

Enforcement of the provisions of this IFC for LTC facilities will be similar to those requirements addressing influenza and pneumococcal vaccinations. We will impose civil money penalties if we determine that the facility has failed to report vaccination data.[59] Education and vaccine administration must be reflected in facility policies and procedures, as well as in staff and resident records. In addition, NHSN reporting of vaccine and therapeutics must be reflected in facility policies and procedures, with evidence of data submission. For ICFs–IID, education and administration of the vaccine must be reflected in facility policies and procedures, as well as in staff and client records. Updated guidance and information on reporting and enforcement of these new requirements will be issued when this IFC is published.

We specify at §§ 483.80(d)(3)(i) and 483.460(a)(4)(i) that COVID–19 vaccines must be offered when available. If a facility does not have access to the vaccine, we expect the facility to provide, upon request, evidence that efforts have been made to make the vaccine available to its residents or clients, and staff. For example, documentation of communications with the facility medical director, the local health department, or listing of vaccination sites may be used to show efforts to make the vaccine available to residents, clients, and staff. Similar to influenza vaccines, if there is a manufacturing delay, we ask the facility to provide sufficient evidence of such. The infection prevention and control plan is designed to allow for documentation of vaccine efforts. While Pharmacy Partnership clinics are currently the most common avenue for delivering COVID–19 vaccines to LTC facilities, we expect all facilities to be prepared to participate in other distribution programs (possibly through local health departments or traditional pharmacies) as the vaccine continues to become more widely available at a multiplicity of sites.

If an individual resident, client, or staff member requests vaccination against COVID–19, but missed earlier opportunities for any reason (including recent residency or employment, changing health status, overcoming vaccine hesitancy, or any other reason), we expect facility records to show efforts made to acquire a vaccination opportunity for that individual. Although we are not establishing formal timeframes within which vaccination must be arranged for new residents, clients, or staff, we expect LTC facilities and ICFs–IID to support vaccination for these individuals as quickly as practicable. Further, we expect personnel records for facility staff and health records for residents and clients to reflect appropriate administration of any multi-dose vaccine series, including efforts to acquire subsequent doses as necessary.

[59] Social Security Act. Section 1819(h)(2)(B)(ii). Accessed at *https://www.ssa.gov/OP_Home/ssact/title18/1819.htm*; and Social Security Act. Section 1919(h)(2)(A)(ii). Accessed at *https://www.ssa.gov/OP_Home/ssact/title19/1919.htm*. Both accessed on April 28, 2021.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the provisions of the rule are finalized, either as proposed or as amended in response to public comments, and take effect, in accordance with the Administrative Procedure Act (APA) (Pub. L. 79–404), 5 U.S.C. 553, and, where applicable, section 1871 of the Act. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Further, 5 U.S.C. 553 requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and a period of not less than 60 days for public comment for rulemaking carrying out the administration of the insurance programs under title XVIII of the Act. Section 1871(b)(2)(C) of the Act and 5 U.S.C. 553 authorize the agency to waive these procedures, however, if the agency for good cause finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. Section 553(d) of title 5 of the U.S. Code ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(i) of the Act also prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date the rule is issued or published. However, section 1871(e)(1)(B)(ii) of the Act permits a substantive rule to take effect before 30 days if the Secretary finds that a waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest.

Furthermore, section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act to be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the change retroactively would be contrary to the public interest. Finally, the Congressional Review Act (CRA) (Pub. L. 104–121, Title II) requires a 60-day delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. 801(a)(3), 808(2).

A. COVID–19 and Populations at Higher Risk

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of international concern.'' On January 31, 2020, pursuant to section 319 of the PHSA, the Secretary determined that a PHE exists for the United States to aid the nation's health care community in responding to COVID–19. On March 11, 2020, the WHO publicly declared COVID–19 a pandemic. On March 13, 2020, the President declared the COVID–19 pandemic a national emergency.

Over 569,000 individuals have lost their lives to COVID–19 in the United States as of April 27, 2021,[60] including more than 131,000 LTC facility residents, or close to one tenth of the average national LTC facility resident census of 1.4 million.[61] In recognition of the susceptibility of their residents, clients, and staff, LTC facilities and other congregate settings, including ICFs–IID, have been prioritized for vaccination. The data show that COVID–19 cases are declining in LTC facilities concurrently with increasing vaccination among residents and staff, but as noted below, we are concerned that the rate of vaccination in LTC facilities may slow in the absence of regulation and the conclusion of the Pharmacy Partnership program, especially in light of consistent, frequent resident and staff turnover in these facilities and the cold storage chain challenges that exist with two of the three currently available vaccines that make obtaining and providing the vaccine more challenging for small facilities that do not have the necessary storage equipment. Ensuring the health and safety of all Americans, including Medicare and Medicaid beneficiaries, and health care workers is of primary importance. This IFC directly supports that goal by requiring education about and offer of COVID–19 vaccination for LTC facility and ICF–IID residents, clients, and staff. This IFC also requires reporting of COVID–19 vaccination status and use of COVID–19 therapeutics of LTC facility residents and staff, which will provide vital data that CMS, CDC, and other public health entities can use to target our outreach and resources in support of vaccination.

B. Supporting Vaccine Distribution and Uptake

In response to the COVID–19 pandemic, pharmaceutical developers around the world began development of vaccine that would prevent severe illness and death and they have produced several vaccines authorized for use in the United States. Because the first cohort of authorized vaccines require specialized handling, and LTC facility residents have been at higher risk of severe illness from COVID–19, CDC established the Pharmacy Partnership for Long-Term Care (LTC) Program, which has facilitated on-site vaccination of residents and staff at more than 63,000 enrolled nursing homes and assisted living facilities while reducing the burden on facility administrators, clinical leadership, and health departments. At no cost to facilities, the program has provided end-to-end management of the COVID–19 vaccination process, including cold chain management, on-site vaccinations, and fulfillment of reporting requirements.

While the Pharmacy Partnerships have had much success in ensuring timely vaccine access to many LTC facility residents and staff, we note that not all such individuals were able to receive vaccine under the program. Internal CDC data show that approximately 2,500 or about 16 percent of CMS-certified SNFs (a subset of LTC facilities enrolled as Medicare providers) that are enrolled in NHSN did not participate in the Pharmacy Partnership program. LTC facility residents are unable to live independently, and generally are unable to access the vaccine without significant assistance from the facility in which they reside or from family members or caregivers. As we currently do not require LTC facilities to report vaccination status within their facility, we have no comprehensive way of knowing whether residents or staff of those facilities have acquired the vaccine through avenues outside the Partnerships. Ensuring that individuals residing in LTC facilities that did not participate in the Pharmacy Partnerships have access to vaccination against COVID–19 is critical so as to expeditiously ensure that residents are protected.

Most LTC facilities participated in the Pharmacy Partnerships but the Partnerships concluded in March 2021. The Pharmacy Partnership program was designed as time-limited effort designed to quickly vaccinate thousands of facility residents per week.

Ending the program without appropriate requirements to ensure facilities continue to seek vaccination opportunities for their residents and staff puts future incoming LTC facility residents and staff at risk. Turnover of both LTC facility residents (admissions and discharges) and staff can be significant. It is difficult to estimate the number of admissions and discharges in LTC facilities as 20 to 25 percent of beds are often reserved for shorter term (weeks to months) rehabilitation stays, while other individuals reside in the facility for years. That said, resident turnover within a year may be significant, possibly up to 40 percent based on internal CMS estimates. Staff turnover is more easily considered, with some estimates as high as 100 percent for certain facilities within a year,[62] and if a facility finds itself with a large portion of its community being unvaccinated, all residents and staff may again face a higher risk of infection, similar to the risk levels during the early months of the pandemic. For example, if final Partnership vaccination rates reach even 90 percent (an illustrative example as we do not have final or complete data) of the residents present in the first 3 months of 2021, turnover during the rest of the year may be such that by year-end as few as two-thirds of LTC residents present at some point during the year would have been vaccinated absent a continuing and effective effort.

Turnover rates demonstrate there will be an ongoing need for new resident or staff vaccinations. For example, when the Pharmacy Partnership completes its time commitment, it is likely that it will have seen only about half of the persons who will reside or work in these facilities in 2021. Even if two-thirds of

[60] *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[61] LTC Facility deaths are from COVID–19 Nursing Home Data, CMS, Week Ending 3/28/2021, at *https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/.*

[62] *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00957.*

all newly hired staff and newly admitted residents have been vaccinated when they start employment or begin residency, turnover is so high that we estimate an excess of two million persons may still need vaccination in the first year after this rule takes effect. It is critically important that facilities are required to continue to offer vaccination to their residents and staff on an ongoing basis.

Also, we note that some individuals declined the vaccine when it was first offered; approximately 22 percent of LTC facility residents and 62 percent of LTC staff [63] initially declined the vaccine, but provisional CDC data suggest that uptake increased over time as the safety and effectiveness of the vaccines has become better understood, and approaches that ameliorate vaccine hesitancy have been identified. For residents and staff who overcome vaccine hesitancy, it is critical to their health and well-being that they are able to get the vaccine when they are ready to receive it.

All of the concerns that warrant immediate COVID–19 vaccination rulemaking for LTC facilities are also applicable to ICFs–IID. ICF–IID clients continue to be at high risk of serious illness from COVID–19 due to their participation in congregate living and must have ongoing access to the vaccine. While there are no data regarding client and staff turnover rates in ICFs–IID, it is reasonable to assume that staff turnover rates may be as high as those in LTC facilities (see the RIA section of this preamble).

C. Data for COVID–19 Vaccine Reporting: Targeting Resources

Our knowledge of the effects of COVID–19 vaccination in LTC facilities comes from several sources, including reporting by Partnership pharmacies and voluntary reporting by some facilities through NHSN. Direct voluntary vaccination reporting to NHSN by LTC facilities has been very low, with less than 20 percent of facilities reporting on vaccinations through NHSN. Unfortunately, we are unable to examine the effects of accepting or declining participation in the Pharmacy Partnerships because the data are incomplete for LTC facilities and ICFs–IID. Requiring LTC facilities to report on resident and staff vaccination status, in conjunction with the existing COVID–19 testing data, would provide the data necessary to identify the outcomes of Pharmacy Partnership participation and determine vaccine uptake targets. It would also ensure we can identify and address barriers to completing a vaccination series, such as missed or declined second doses.

If this lack of data continues, CDC will have insufficient information upon which to provide support to or revise COVID–19 infection, prevention, and control measures for LTC facilities. While recommendations for routine staff testing could be linked to vaccination rates in each LTC facility (and thus reduce burden on facilities with adequate rates of vaccine coverage), CDC will not have enough data to assess a change in recommendation without full national participation in COVID–19 vaccination reporting by CMS-certified LTC facilities.

Declining infection rates in LTC facilities in early 2021 suggest that vaccination, along with implementation of the full complement of non-pharmaceutical interventions, including engineering and administrative controls, has reduced the risk of illness and death from COVID–19 for LTC facility residents. Without the reporting mandate, CMS will have no timely way of monitoring whether LTC facilities are complying with the requirement to offer vaccination. Further, such mandatory reporting allows health care agencies and regulators to better evaluate the impact and importance of vaccination. Without a reporting requirement, we will have no way to identify those nursing homes with low vaccination rates so that they can be supported by educational outreach and their residents and staff protected by vaccination.

Unfortunately, we have significant data gaps about the effects of COVID–19 and vaccination rates among ICF–IID clients, with fewer than 80 ICFs–IID voluntarily reporting vaccination data through NHSN. While we recognize that it is impractical to require ICFs–IID to report COVID–19 information to NHSN immediately, we believe that encouraging voluntary reporting is a critical first step in gaining data to help us understand the effects of the pandemic on clients and staff, supporting uptake of COVID–19 vaccine in this community.

D. Moving Forward

For the reasons discussed above, it is critically important that we implement the policies in this IFC as quickly as possible. As the nation continues to address the health impacts of COVID–19, we find good cause to waive notice and comment rulemaking as we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment rulemaking procedures. For the same reasons, because we cannot afford sizable delay in effectuating this IFC, we find good cause to waive the 30-day delay in the effective date and, moreover, to make this IFC effective 10 calendar days after this rule is filed for public inspection in the **Federal Register**.

In this IFC, we follow on policy issued in the September 2, 2020, COVID–19 IFC, which revised regulations to strengthen CMS' ability to enforce compliance with Medicare and Medicaid LTC facility requirements for reporting information related COVID–19 and established a new requirement for LTC facilities for COVID–19 testing of facility residents and staff. Since the publication of the September IFC, the FDA has issued EUAs for multiple vaccines developed to prevent the spread of SARS-CoV–2.

We anticipate evaluating public input and evolving science before finalizing any requirements.

For this IFC, we believe it would be impractical and contrary to the public interest for us to undertake normal notice and comment procedures and to thereby delay the effective date of this IFC. We find good cause to waive notice of proposed rulemaking under the APA, 5 U.S.C. 553(b)(B), and section 1871(b)(2)(C) of the Act. For those same reasons, we find it is impracticable and contrary to the public interest not to waive the delay in effective date of this IFC under the APA, 5 U.S.C. 553(d), section 1871(e)(1)(B)(i) of the Act, and the CRA, 5 U.S.C. 801(a)(3). Therefore, we find there is good cause to waive the delay in effective date pursuant to the APA, 5 U.S.C. 553(d)(3), section 1871(e)(1)(B)(ii) of the Act, and the CRA, 5 U.S.C. 808(2).

We are providing a 60-day public comment period.

IV. Collection of Information (COI) Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

[63] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7005e2.htm.*

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comments on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

For the estimated costs contained in the analysis below, we used data from the United States Bureau of Labor Statistics to determine the mean hourly wage for the positions used in this analysis. 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 .50 or more, the cost was rounded up to the next dollar. If it was .49 or below, the total cost was rounded down to the next dollar. The total costs used in this analysis are indicated in the chart below.

TABLE 1—TOTAL HOURLY COSTS BY POSITION

Position	Mean hourly wage	Total cost
LTC and ICF–IID: RN/IP	[64] $33.53	$67
LTC: Director of Nursing & ICF–IID: Administrator	[65] 46.78	94
LTC: Medical Director	[66] 84.57	169
LTC: Financial Clerk	[67] 20.40	41

A. Long-Term Care Facilities

1. ICRs Regarding the Development of Policies and Procedures for § 483.80(d)(3)

At § 483.80(d)(3), we require that LTC facilities develop policies and procedures to ensure that each resident and staff member is educated about the COVID–19 vaccine. Specifically, before offering the COVID–19 vaccine, all staff members and residents or resident representatives must be provided with education regarding the benefits and risks and potential side effects associated with the vaccine. When the vaccine is available to the facility, each resident and staff member is offered COVID–19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized. If an additional dose of the COVID–19 vaccine that was administered, a booster, or any other vaccine needs to be administered, the resident, resident representative, and staff member must be provided with the current information regarding the benefits and risks and potential side effects for that vaccine, before the LTC facility requests consent for administration of that dose. The resident, resident representative, and staff member must be provided the opportunity to refuse the vaccine and change their decision if they decide to take the vaccine. Finally, the resident's medical record includes documentation that indicates, at a minimum, that the resident or resident representative was provided education regarding the benefits and potential risk associated with the COVID–19 vaccine, and that the resident either received the complete COVID–19 vaccine (series or single dose) or did not receive the vaccine due to medical contraindications or refusal. The estimates that follow are largely based on upon our experience with LTC facilities. However, given the uncertainty and rapidly changing nature of the pandemic, we acknowledge that there will likely need to be significant revisions over time as LTC facilities gain experience with these requirements. As previously discussed, we do not have current reporting data on facility compliance with COVID–19 vaccination best practices of the kinds established in this rule. We welcome comments that might improve these estimates.

Based upon our experience with LTC facilities, we believe that some of these facilities have already developed the required policies and procedures. However, since we do not have any reliable method to make an estimate of how many or what percentage of LTC facilities have done so, we will base our estimate for this ICR on all 15,600 LTC facilities needing to develop new policies and procedures in order to comply with this requirement. These facilities also need to review the policies and procedures to ensure they are up-to-date and make any necessary changes. We believe these activities would be performed by the infection preventionist (IP), director of nursing (DON), and medical director in the first year and the IP in subsequent years as analyzed below.

In the first year, the IP would need to develop the policies and procedures by conducting research and obtaining the necessary information and materials to draft the policies and procedures. The IP would need to work with the medical director and DON to develop and finalize the policies and procedures. For the IP, we estimate that this would require 10 hours initially to develop the policies and procedures, and one hour a month thereafter to review and make changes or updates as needed, for a total of 21 hours (10 hours initially and 1 hour for the 11 months thereafter). According to Table 1 above, the IP's total hourly cost is $67. Thus, for each LTC facility the burden for the IP would be 21 hours at a cost of $1,407 (21 hours × $67). For the IPs in all 15,600 LTC facilities, the burden would be 327,600 hours (21 hours × 15,600 facilities) at an estimated cost of $21,949,200 ($1,407 × 15,600). For subsequent years, the IP would need to review the policies and procedures and make any updates or changes to them. Hence, we estimate that the IP would need 12 hours annually (1 hour × 12 months) at a cost of $804 (12 hours × $67). For all LTC facilities, the annual burden would be 187,200 hours (12 × 15,600) at a cost of $12,542,400 (15,600 × $804).

As discussed above, the development and approval of these policies and procedures would also require activities by the medical director and the DON. Both the medical director and the DON would need to have meetings with the

[64] Bureau of Labor Statistics. Occupational Employment and Wages, May 2019. 29–1141 Registered Nurses. Accessed at *https://www.bls.gov/oes/current/oes291141.htm.* Accessed on March 18, 2021.

[65] Bureau of Labor Statistics. Occupational Employment and Wages, May 2019. 11–9111 Medical and Health Services Managers. Nursing Care Facilities (Skilled Nursing Facilities). Accessed at *https://www.bls.gov/oes/current/oes119111.htm.* Accessed on February 17, 2021.

[66] Bureau of Labor Statistics. Occupational Employment and Wages, May 2019. 29–1228 Physicians, All Other; and Ophthalmologists, Except Pediatric. General Medical and Surgical Hospitals. Accessed at *https://www.bls.gov/oes/current/oes291228.htm#(5).* Accessed on February 17, 2021.

[67] Bureau of Labor Statistics. Occupational Employment and Wages, May 2019. 43–3099 Financial Clerks, All Others. Accessed at *https://www.bls.gov/oes/current/oes433099.htm.* Accessed on March 23, 2021.

IP to discuss the development, evaluation, and approval of the policies and procedures. We estimate that this would require 4 hours for both the medical director and DON. According to Table 1 above, the total hourly cost for a medical director is $169. For each LTC facility, this would require 4 hours for the medical director during the first year at an estimated cost of $676 (4 hours × $169). For the first year, the burden would be 62,400 (4 × 15,600) at an estimated cost of $10,545,600 ($676 × 15,600). For subsequent years, the medical director might need to spend time reviewing or attending meetings to discuss any updates or changes to the policies and procedures; however, that would be a usual and customary business practice. Therefore, these activities for the medical director associated with updating or changing the policies and procedures are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

For the DON, we have estimated that the development of policies and procedures would also require 4 hours. According to the chart above, the total hourly cost for the DON is $94. The burden in the first year for the DON in each LTC facility would be 4 hours at an estimated cost of $376 (4 hours × $94). The first year burden would be 62,400 hours (4 × 15,600) at an estimated cost of $5,865,600 ($376 × 15,600). For subsequent years, the DON would likely need to spend time reviewing or attending meetings to discuss any updates or changes to the policies and procedures; however, that would be a usual and customary business practice. Therefore, these activities for the DON associated with updating or changing the policies and procedures are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

Therefore, for all 15,600 LTC facilities in the first year, the estimated burden for this ICR would be 452,400 hours (327,600 + 62,400 + 62,400) at a cost of $38,360,400 ($21,949,200 + $10,545,600 + $5,865,600).

In subsequent years, all 15,600 LTC facilities would have the same burden. The burden for each LTC facility would be 12 hours at an estimated cost of $804 (12 hours × $67) for the IP. Hence, for all 15,600 LTC facilities, the burden would be 187,200 (12 × 15,600) at an estimated cost of $12,542,400 ($804 × 15,600). The requirements and burden will be submitted to OMB under OMB control number 0938–1363 (Expiration Date 06/30/2022).

2. ICRs Regarding LTC Facilities Offering the COVID–19 Vaccine and Obtaining and Documenting Consent for § 483.80(d)(3)(ii) Through (iv)

At § 483.80(d)(3)(i), we require that the facility offer the COVID–19 vaccine to each staff member and resident, when the vaccination is available to the facility, unless the vaccine is medically contraindicated, the resident has already been vaccinated, or the resident or the resident representative has already refused the vaccine. We believe that the LTC facility will offer the vaccine to the staff or resident at the same time the facility provides the education required by § 483.80(d)(3)(ii) and (iii). We note that for LTC facilities contracted with the Pharmacy Partnership, the education and offering of the vaccine are being done by the participating pharmacy. We assume that this cost is about the same as the preceding estimates, so that the first year costs would be about the same whether performed entirely in-house by facility staff or by pharmacy staff who visit the facility.

We note that the LTC facility or the pharmacy would also have to offer the vaccine to the staff member or resident and have that staff member, resident, or resident representative, complete screening for any contraindication or precautions, and for the resident to consent to the vaccination or indicate refusal. These costs are not paperwork burden and are covered in the RIA that follows.

As indicated in the next section, the facility must also ensure that the provision of the education and the resident's decision must be documented in the resident's medical record. If there is a contraindication to the resident having the vaccination, the appropriate documentation must be made in the resident's chart. Documentation regarding a resident's medical care is a usual and customary business practice for a health care provider. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

3. ICRs Regarding Staff Education Requirements in § 483.80(d)(3)(ii) Through (iv)

At § 483.80(d)(3)(ii), we require that the LTC facility provide all of its staff with education regarding the benefits and potential risks of the COVID–19 vaccine. This would require that the LTC facility develop or choose educational materials for this staff training. We expect that most if not all LTC facilities will use resources developed by other entities as there is a considerable amount of free information on COVID–19 and vaccines available online. The CMS Nursing Home COVID–19 training program has five modules designed for the frontline clinical staff and ten modules for nursing home management staff (building maintenance staff and other support staff would not take these particular courses). The training is online, at *http://QSEP.cms.gov,* and is summarized in a CMS press release that can be found at *https://www.cms.gov/newsroom/press-releases/cms-releases-nursing-home-covid-19-training-data-urgent-call-action.* In addition, both CDC and FDA provide information on the COVID–19 vaccines online.[68] [69] Finally, we expect that trade publications and other public sources would provide training materials that might complement or substitute for the CMS materials. We believe this educational material would likely be selected by the IP. The IP would need to review the information available on the vaccines, determine what information needs to be presented to staff, and gather that information as appropriate for their facility's staff. We estimate that it would take an average of 4 hours for the IP to accomplish these tasks. Thus, for each LTC facility to meet this requirement would require 4 burden hours at an estimated cost of $268 (4 × $67). For all 15,600 LTC facilities, the burden would be 62,400 burden hours (4 × 15,600) at an estimated cost of $4,180,800 (4 × $67 × 15,600 facilities).

At § 483.80(d)(3)(iii), we require that LTC facilities provide their residents or resident representatives with education regarding the benefits and risks and potential side effects associated with the COVID–19 vaccine. We believe that the education provided to staff and residents or resident representatives will be identical or virtually the same. Hence, we believe that it will not require any additional time or burden to develop the educational materials for the residents and resident representatives. According to § 483.10(g)(3), the facility must ensure that information is provided to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can

[68] CDC. Communication Resources for COVID–19 Vaccines. Access at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/resource-center.html.* Updated March 16, 2021. Accessed on March 23, 2021.

[69] FDA. COVID–19 Vaccines. Access at *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.* Updated March 18, 2021. Accessed on March 23, 2021.

understand. Thus, we expect that this required education would be in a language that the resident or the resident representative understands. Language translations for residents may be available in many facilities from staff, and are virtually always available on demand through services, such as Language Line. LTC facilities are already required to provide information in an alternative format or language the resident or resident representative understands. Any additional costs are minor and are discussed in more detail in the RIA below. At § 483.80(d)(3)(iv), we require that the LTC facility must provide to the staff, resident, or the resident representative, in situation where the vaccination process requires one or more doses of vaccine, up-to-date information regarding the vaccine, including any changes in the benefits or risks and potential side effects associated with the COVID–19 vaccine, before requesting consent for administration of each additional vaccinations. This would require that the IP remains up-to-date on information regarding COVID–19 vaccines and ensures the information provided to the resident and the resident representative before requesting consent for the administration of each additional dose of vaccine includes current information on the benefits and potential risks associated with the vaccine. We believe that this activity would require that the IP routinely review CDC and FDA websites for updates and make any necessary changes to the education materials used by the LTC facility. We estimate that this would require 6 hours of an IP's time annually. Thus, for each LTC facility to meet this requirement would require 6 burden hours at an estimated cost of $402 (6 × $67). For all LTC facilities, the annual burden would be 93,600 (6 hours × 15,600) hours at an estimated cost of $6,271,200 ($402 × 15,600). We estimate that the burden to the LTC facilities will be similar in subsequent years due to the large turnover in these facilities. The requirements and burden will be submitted to OMB under OMB control number 0938–1363 (Expiration Date 6/30/2022).

4. ICRs Regarding the Documentation Requirements in § 483.80(d)(3)(vi) and (vii)

At § 483.80(d)(3)(vi), we require that the facility ensure that the resident's medical record is documented with, at a minimum, that the resident or resident representative was provided education regarding the benefits and potential risks associated with the COVID–19 vaccine and that the resident either received the COVID–19 vaccine, did not receive the vaccine due to medical contraindications, or refused the vaccine. This would require that a health care provider, probably a licensed nurse, would retrieve the resident's medical record and document that the education was provided and whether the resident or resident representative had consented or refused the vaccine or whether the vaccine was contraindicated. We estimate that this would require only a few seconds per resident, but estimate no costs as maintaining a medical record is a usual and customary business practice. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

As discussed above in section II.A. of this rule, the LTC facility would also be required to document that the required education was provided to its staff that must include the benefits and potential risks associated with of the COVID–19 vaccine as set forth in § 483.80(d)(3)(ii). Section 483.80(d)(3)(vii) sets forth that the LTC facility must maintain documentation on its staff regarding the education provided; that the staff person was offered the COVID–19 vaccine or information on obtaining the vaccine, and his or her vaccine status and related information indicated by the NSHN. This would require that a staff person document the required information in the staff person's record. We estimate that this would require one half-hour per month per facility. According to Table 1 above, the total hourly cost of a financial clerk is $41. For each LTC facility, we estimate that the burden for this activity would be 6 hours at an estimated cost of $246 ($41 × 12 × .5). For all LTC facilities, this would require 93,600 (12 × .5 × 15,600) burden hours at an estimated cost of $3,837,600 ($41 × 12 × .5 × 15,600). We estimate that the burden to the LTC facilities will be similar in subsequent years due to the large turnover in these facilities. The requirements and burden will be submitted to OMB under OMB control number 0938–1363.

5. ICRs Regarding the Reporting Requirements to CMS and CDC (NSHN) § 483.80(g)(1)(viii) and (ix)

Section 483.80(g)(1)(viii) requires LTC facilities to electronically report information about COVID–19 in a standardized format to the NHSN about the COVID–19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID–19 vaccine received, COVID–19 vaccination adverse events. The LTC facility must also report the therapeutics administered to residents for treatment of COVID–19.

We believe the IP would do this weekly reporting to the NHSN, because this reporting would require information on the therapeutics that were administered to resident for treatment of COVID–19. We believe this additional reporting would require about 30 minutes or .5 hour each week for the IP. Thus, for each LTC facility, this burden would be 26 hours (.5 × 52 weeks) at an estimated cost of $1,742 ($67 × 26) annually. For all LTC facilities, the burden would be 405,600 hours (26 × 15,600) at an estimated cost of $27,175,200 ($1,742 × 15,600) annually.

Thus, the total annual burden for all LTC facilities to comply with the requirements in this IFC in the first year is 1,107,600 (452,400 + 62,400 + 93,600 + 93,600 + 405,600) hours at an estimated cost of $79,825,200 ($38,360,400 + $4,180,800 + $6,271,200 + $3,837,600 + $27,175,200). In subsequent years, the burden would be 780,000 hours (187,200 + 93,600 + 93,600 + 405,600) at an estimated cost of $49,826,400 ($12,542,400 + $6,271,200 + $3,837,600 + $27,175,200). See Table 2 below. The requirements and burden will be submitted to OMB under OMB control number 0938–1363.

TABLE 2—TOTAL COST FOR COI REQUIREMENTS FOR ALL LTC FACILITIES

COI requirements	First year		Subsequent years	
	Burden hours	Costs	Burden hours	Costs
§ 483.80(d)(3) Developing Policies and Procedures	452,400	$38,360,400	187,200	$12,542,400
§ 483.80(d)(3)(ii) & (iii) Developing education materials for staff members and residents and residents' Representatives	62,400	4,180,800	N/A	N/A

TABLE 2—TOTAL COST FOR COI REQUIREMENTS FOR ALL LTC FACILITIES—Continued

COI requirements	First year		Subsequent years	
	Burden hours	Costs	Burden hours	Costs
§ 483.80(d)(3)(iv) Keeping vaccine information up-to-date and Making necessary changes	93,600	6,271,200	93,600	6,271,200
§ 483.80(d)(3)(vi) and (vii) Documentation requirements	93,600	3,837,600	93,600	3,837,600
§ 483.83(d)(3)(viii) and (ix) NHSN Reporting	405,600	27,175,200	405,600	27,175,200
Totals	1,107,600	79,825,200	780,000	49,826,400

B. Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICF–IIDs)

1. ICRs Regarding the Development of Policies and Procedures for § 483.460(a)(4)

At new § 483.460(a)(4), we require that ICFs–IID develop policies and procedures to ensure that each client or client's representative and staff member is educated about the COVID–19 vaccine. Specifically, before offering the COVID–19 vaccine, all staff members and clients or client representatives must be provided with education regarding the benefits and risks and potential side effects associated with the vaccine. When the vaccine is available to the facility, each client and staff member is offered COVID–19 vaccine unless the immunization is medically contraindicated or the client or staff member has already been immunized. If an additional dose of the COVID–19 vaccine that was administered, a booster, or any other vaccine needs to be administered, the client, client representative, and staff member must be provided with the current information regarding the benefits and risks and potential side effects for that vaccine, before the ICF–IID requests consent for administration of that dose. The client, client's representative, and staff member must be provided the opportunity to refuse the vaccine and change their decision if they decide to take the vaccine. Finally, the client's medical record must include documentation that indicates, at a minimum, that the client or client's representative was provided education regarding the benefits and risks and potential side effects of the COVID–19 vaccine and each does of the COVID–19 vaccine administered to the client or if the client did not receive a dose due to medical contraindications or refusal.

We believe that developing these policies and procedures would require a RN to gather the necessary information and materials and draft the policies and procedures. The facility must also ensure that these materials are in an accessible format for the client and his or her representative. It must be in a language that they understand and in a format that is accessible to them, such as Braille or large print for a person who is visually-impaired or in American Sign Language for a person who is hearing-impaired. The RN would need to work with an ICF–IID administrator who would likely provide input and guidance in developing the policies and procedures and would need to approve them before they go before the governing body for approval. For the RN, we estimate that this would require 5 hours initially, and 30 minutes or .5 hour a month thereafter to review for updated information to determine if any changes need to be made to the policies or procedures and then make any necessary changes. According to Table 1 above, the total hourly cost for an RN is $67. We estimate that for each ICF–IID, the burden would be 10.5 hours (5 hours initially + 5.5 (11 × .5)) for the RN during the first year at an estimated cost of $704 ($67 × 10.5 hours). Assuming 5,772 ICFs–IID, for the first year the burden for all facilities would be 60,606 burden hours (10.5 × 5,772 facilities) at an estimated cost of $4,060,602 (10.5 × $67 × 5,772). In subsequent years, the burden for this activity for each facility would be 6 hours (.5 hour × 12 months) at an estimated cost of $402 (6 × $67). In subsequent years the burden for all facilities would be 34,632 (6 × 5,772) burden hours at an estimated cost of $2,320,344 (6 × $67 × 5,772).

For the ICF–IID administrator, we believe it would require 3 hours to work with the RN in developing the policies and procedures and give final approval before taking the policies and procedures to the governing body for approval. We believe that the administrator would likely make a salary similar to that of a manager in the LTC setting, like that for the DON salary as discussed above. Therefore, we estimate that an ICF–IID administrator's hourly mean salary is about $94. Thus, for each ICF–IID, the burden hours for the administrator would be 3 hours at an estimated cost of $282 (3 × $94). For all 5,772 ICFs–IID, the total burden for the administrator would be 17,316 hours (3 × 5,772 facilities) at an estimated cost of $1,627,704 ($282 × 5,772 facilities).

As discussed above, the ICF–IID administrator would need to obtain approval from the ICF–IID's governing board for the policies and procedures. Since the review and approval of policies and procedures should be encompassed within the governing board's responsibilities, this activity would be usual and customary and exempt from the information collection estimate. In addition, in subsequent years the ICF–IID administrator might need to spend time reviewing or attending a meeting to discuss any updates to the policies and procedures; however, that would also be a usual and customary business practice. Therefore, this activity is exempt from the PRA in accordance to 5 CFR 1320.3(b)(2).

Therefore, for all ICFs–IID, the total annual burden in the first year for the required policies and procedures would be 77,922 burden hours (60,606 + 17,316) at an estimated cost of $5,688,306 ($4,060,602 + $1,627,704). In subsequent years, the burden would only be for the RN and it would be 34,632 burden hours at an estimated cost of $2,320,344. The requirements and burden will be submitted to OMB under OMB control number 0938-New.

2. ICRs Regarding the ICFs–IID Offering the Vaccine and Obtaining and Documenting Consent in § 483.460(a)(4)(i)

At new § 483.460(a)(4)(i), we require that the ICF–IID offer the COVID–19 vaccine to each staff member and client, when the vaccination is available to the facility, unless the vaccine is medically contraindicated, the client has already been vaccinated, or the client or the client representative has already refused the vaccine. We believe that the ICF–IID will offer the vaccine to the client or the client representative at the same time the facility provides the education required by new § 483.460(a)(4)(ii). This activity would require that the ICF–IID offer the vaccine to the staff member or

resident and have that staff member, client, or client representative complete screening for any contraindication or precautions, and for the client or client representative consent to the vaccination or indicated refusal. This is not a paperwork burden and are covered in the RIA that follows.

3. ICRs Regarding the Education Requirements in § 483.460(a)(4)(ii), (iii), and (iv)

At new § 483.460(a)(4)(ii), we require that the ICF–IID provide all of its staff with education regarding the benefits and potential risks associated with of the COVID–19 vaccine. New § 483.460(a)(4)(iii) requires that the ICF–IIF to provide each client or the client's representative education regarding the benefits and risks and potential side effects associated with the vaccine. In addition, new § 483.460(a)(4)(iv) requires that the ICF–IID, in situations where there is an additional dose of the COVID–19 vaccine that was administered, a booster, or any other vaccine needs to be administered, must provide the client, client's representative, and staff member with the current information regarding the benefits and risks and potential side effects for that vaccine, before the facility requests consent for administration of that dose. We believe that all of the education provided by the ICF–IID to the client, client's representative and the staff would be virtually identical.

For the initial education, the ICF–IID would be required to develop educational materials by reviewing available resources on COVID–19 vaccines. We expect that most if not all ICFs–IID will use resources developed by other entities as there is a considerable amount of free information on COVID–19 and its vaccines available online. For example, CDC and FDA provide information on the COVID–19 vaccines online.[70] [71] Finally, we expect that trade publications and other public sources would provide training materials. We believe this educational material would likely be selected by the RN. The RN would need to review the information available on the vaccines, determine what information needs to be presented to the client, client's representative and staff members, and gather that information as appropriate. An ICF–IID administrator would likely work with the RN and need to approve the final educational material. We estimate that it would initially require 7 hours and thereafter 6 hours annually to review for updates and make those changes to the educational materials for a total of 13 hours for the RN to accomplish these tasks in the first year. Thus, for each ICF–IID, the burden for the RN would require 13 burden hours at an estimated cost of $871 (13 × $67). For all 5,772 ICFs–IID so the burden for all facilities would be 75,036 burden hours (13 hours × 5,772 facilities) at an estimated cost of $5,027,412 (5,772 hours × $871).

For the education required in subsequent years, the RN would need to ensure that the information regarding COVID–19 vaccines that is provided to the staff, client and the client's representative before requesting consent for each additional dose of the vaccine is current. We believe that this activity would require the RN to routinely review CDC and FDA websites for updates and make any necessary changes to the education materials used by the ICF–IID. We estimate that this would require 6 hours of an IP's time annually. Thus, for each ICF–IID to meet this requirement would require 6 burden hours at an estimated cost of $402 ($67 × 6 hours). For all ICFs–IID, meeting this requirement would require 34,632 burden hours (6 hours × 5,772 facilities) at an estimated cost of $2,320,344 (5,772 × $402). The requirements and burden will be submitted to OMB under OMB control number 0938-New.

4. ICRs Regarding the Documentation Requirements in § 483.460(a)(4)(vi) and (f)

At new § 483.460(a)(4)(vi), the ICF–IID must ensure that the client's medical record is documented with, at a minimum, that the client or client's representative was provided education regarding the benefits and potential risks associated with the COVID–19 vaccine and that the resident either received the COVID–19 vaccine or did not receive the vaccine due to medical contraindications, or refused the vaccine. This would require that the RN to retrieve the client's medical record and document the required information. We estimate that this would require only a few seconds per client but estimate no costs as maintaining a medical record is a usual and customary business practice. Therefore, this activity is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

At new § 483.460(f), the ICF–IID is required to, at a minimum, document that their staff were provided education regarding the benefits and potential risks associated with the COVID–19 vaccine and that each staff member was offered the vaccine or was provided information on how to obtain it. This would require that a staff person document that these tasks were accomplished. We estimate that this would require one quarter or 0.25 hour per month per facility and that this task would be performed by administrative staff, probably a financial clerk. According to Table 1 above, the total hourly cost for a financial clerk of $41. For each ICF–IID it would require 3 hours annually (0.25 × 12) at an estimated cost of $123 ($41 × 3 hours). For all ICFs–IID, the documentation requirements in this IFC this would require 17,316 burden hours (3 hours × 5,772 facilities) at an estimated cost of $709,956 annually (17,316 hours × $123).

In total, we estimate that information collection burden for all ICFs–IID would be about 170,274 hours and $11,425,674 in the first year and 86,580 hours and $5,350,644 in subsequent years.

TABLE 3—TOTAL BURDEN FOR COI REQUIREMENTS FOR ALL ICFS–IID

COI requirement	First year		Subsequent years	
	Burden hours	Costs	Burden hours	Costs
§ 483.460(a)(4) Developing the policies and procedures	77,922	$5,688,306	34,632	$2,320,344
§ 483.460(a)(4)(ii), (iii), and (iv) Education requirements	75,036	5,027,412	34,632	2,320,344
§ 483.460(a)(4)(v) and (f) Documentation requirements	17,316	709,956	17,316	709,956
Totals	170,274	11,425,674	86,580	5,350,644

[70] See FN#71.

[71] See FN#72.

The total burden estimate for the information collection burden in both LTC facilities and ICFs–IID in the first year is 1,277,874 hours (1,107,600 + 170,274) at an estimated cost of $91,250,874 ($79,825,200 + $11,425,674) and in subsequent years the burden is estimated at 866,580 hours (780,000 + 86,580) at a cost of $55,177,044 ($49,826,400 + $5,350,644). The requirements and burden will be submitted to OMB under OMB control number 0938–1363 for the LTC facilities and 0938-New for the ICFs–IID.

TABLE 4—TOTAL COI BURDEN FOR LTC FACILITIES AND ICFS–IID IN THIS IFC

Type of facility	First year		Subsequent years	
	Burden hours	Costs	Burden hours	Costs
LTC Facility	1,107,600	$79,825,200	780,000	$49,826,400
ICFs–IID	170,274	11,425,674	86,580	5,350,644
Totals	1,277,874	91,250,874	866,580	55,177,044

If you comment on this information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this interim final rule.

Comments must be received on/by June 14, 2021.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

The COVID–19 pandemic has precipitated the greatest economic crisis since the Great Depression, and one of the greatest health crises since the 1918 Influenza pandemic. Of the approximately 540,000 Americans estimated to have died from COVID–19 through March 2021,[72] over one-third are estimated to have died during or after a nursing home stay.[73] The development and large-scale utilization of vaccines to prevent COVID–19 cases and have the potential to end future COVID–19-related nursing home deaths. But this huge achievement depends critically on success in vaccination of nursing home residents and staff. This interim final rule will close a gap in current regulations, which are silent on the subject of vaccination to prevent COVID–19.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared an RIA that, taken together with COI section and other sections of the preamble, presents to the best of our ability the costs and benefits of the rulemaking.

This RIA focuses on the overall costs and benefits of the rule, taking into account vaccination progress to date or anticipated over the next year that is not due to this rule, and estimating the likely additional effects of this rule. We analyze both the costs of the required actions and the payment of those costs. As intended under these requirements, this RIA's estimates cover only those costs and benefits that are likely to be the effects of this rule. In the case of the COVID–19 PHE, there is rapid and massive improvement through vaccination, social distancing, treatment, and other efforts already underway, and this rule would have relatively small effects compared to these other efforts, past, present, and future. There are also a number of unknowns that may affect current progress or this rule or both. There are many unknowns (for example, whether vaccine protection lasts only one year rather than 3 years or more, and the possibility of variants that reduce the effectiveness of currently approved vaccines) and we cannot estimate the effects of each of the possible interactions among them, but throughout the analysis we point out some of the most important assumptions we have made and the possible effects of alternatives to those assumptions.

[72] *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[73] For updated data, see CDC daily updates of total deaths at *https://www.cdc.gov/nchs/nvss/vsrr/COVID19/index.htm,* and the Kaiser Family Foundation weekly updates on nursing home deaths at *https://www.kff.org/coronavirus-covid-19/issue-brief/state-covid-19-data-and-policy-actions/,* among other sources.

This rule presents additional difficulties in estimating both costs and benefits due primarily to the fact that an unknown but significant fraction of current LTC staff and residents have already received an explanation of the benefits of vaccination to persons who are elderly or high risk from specific health conditions or both, and the rarely serious risks associated with vaccination (for example, the statistically negligible risk of severe allergic reactions to the vaccine). For a statistically average LTC resident, the average pre-COVID life expectancy if death occurs while in the facility is likely to be on the order of 3 years or fewer but taking into account those who recover and leave the facility and those enrolled for skilled nursing services we estimate overall life expectancies to be about 5 years.[74] We also estimate that vaccination reduces the chance of infection by about 95 percent, and the risk of death from the virus to a fraction of 1 percent.[75] (In Israel, of the first 2.9 million people vaccinated with two doses there were only about 50 infections involving severe conditions resulting from the virus after the 14th day and of these so few deaths that they were not reported in statistical summaries. These data also show that vaccine effectiveness rates are very high for both older and younger recipients. Of those receiving the second vaccine dose, after the 14th day 46 people over the age of 60 became infected and had a severe case, compared to 6 people under the age of 60. Two million nine hundred thousand (2.9 million) people received a second dose; therefore both rates are near zero.)[76]

C. Anticipated Costs of the Interim Final Rule

The previously calculated information collection costs of this rule are one of three major categories of cost. The second large cluster of costs are for the required resident, client, and staff education. In addition, we are requiring facilities to offer COVID–19 vaccines to residents, clients, and staff.

As documented subsequently in this analysis and in a research report on this issue, about 1.5 million individuals work in nursing facilities at any one time.[77] These individuals are at high risk both to become infected with COVID–19 and to transmit the SARS–CoV–2 virus to residents or visitors. Far more than most occupations, nursing home care requires sustained close contact with multiple persons on a daily basis.

In Table 5, we present estimates of total numbers of individuals in the categories regulated under this rule, distinguishing among long-term and shorter-term nursing facility residents, residents and staff, and numbers at the beginning of a year and at any one time during the year, versus the much higher numbers when turnover is taken into account. In this table we assume that the number departing each year is the same as the number entering each year, which is a reasonable approximation to changes in just a few years, but do not take account of the aging of the population over time.

These figures are approximations, because none of the data that is routinely collected and published on resident populations or staff counts focus on numbers of individuals residing or working in the facility during the course of a year or over time. Depending on the average length of stay (that is, turnover) in different facilities, an average population at any one time of, for example, 100 persons would be consistent with radically different numbers of individuals, such as 112 individuals in one facility if one person left each month and was replaced by another person, compared to 365 if one person left each day and was replaced that same day by another person.

In Table 5, we assume it is likely that about 80 or 90 percent of LTC facility residents at the beginning of the year, and 60 or 70 percent of the LTC facility staff at the beginning of the year, were vaccinated by the end of March, due mainly to the efforts of the Partnership. But there are many new persons in each category during the first three months (one fourth of the annual number shown in the second column) and likely fewer of these will have been vaccinated elsewhere. Hence, we assume that the percent of persons who were vaccinated by the end of March is only 70 percent of long-term care residents, 40 percent of skilled nursing care residents, and 60 percent of the LTC facility staff serving both types of residents. The estimated numbers for ICFs–IID are lower because few residents or staff were eligible for vaccination from any source other than the Partnership in the first three months of the year. The estimated numbers of ICF–IID residents and staff, and turnover rates, are particularly rough estimates since there are no published sources that we have found that contain such estimates. We assume that staff turnover is about as high as in LTC facilities, but that resident turnover is considerably lower since resident mortality is not a major factor.

The estimate that 53 percent of these LTC facility and ICF–IID populations as of the end of March were actually vaccinated is simply a weighted average of these numbers. The second and third sections of Table 5 show how these numbers are split between residents and staff, and LTC facilities and ICFs–IID, respectively. This table estimates that during the first year after the issuance of this regulation, as many people will be candidates for vaccination in these facilities as during the first three months of calendar year 2021 (see last column).

TABLE 5—ESTIMATES OF NUMBER AND VACCINATION STATUS OF RESIDENTS AND STAFF
[Thousands]

	Beginning of year 2021*	New during 2021	Total for 2021	Percent vaccinated by March 31	Number vaccinated by March 31	Remaining vaccination candidates 2021	New candidates 1st quarter 2022	Total first year candidates**
Long-Term Care Residents	1,200	400	1,600	70	1,120	480	100	580
Skilled Nursing Care Residents	200	2,100	2,300	40	920	1,380	525	1,905

[74] At age 80, the average life expectancy of a male is about 8 years and of females about 10 years, or an overall average of about 9 years. Long-term care nursing home residents, however, have shorter life expectancies because they have severe health problems or would not have been admitted to a facility. For those who die while in a facility the average life expectancy is about two years. But some recover and leave so we have used five years as a reference point. See discussion at David B. Reuben, ''Medical Care for the Final Years of Life: ''When you're 83, It's not going to be 20 years,'' '' JAMA, Dec. 23, 2009, 2686–2694.

[75] For patients in skilled nursing facilities, average length of stay is less than a month. Hence, turnover is far higher.

[76] See Dvir Aran, Estimating real-world COVID–19 vaccine effectiveness in Israel using aggregated counts, medRxiv, February 28, 2021, at *https://www.medrxiv.org/content/10.1101/2021.02.05.21251139v3.full.pdf* and Noa Dagan et al., ''BNT162b2 mRNA Covid–19 Vaccine in a Nationwide Mass Vaccination Setting,'' The New England Journal of Medicine, 2/24/2021, at *https://www.nejm.org/doi/full/10.1056/NEJMoa2101765.*

[77] Kaiser Family Foundation, COVID–19 and Workers at Risk: Examining the Long-Term Care Workforce, April 23, 2020, at *https://www.kff.org/coronavirus-covid-19/issue-brief/covid-19-and-workers-at-risk-examining-the-long-term-care-workforce/.*

TABLE 5—ESTIMATES OF NUMBER AND VACCINATION STATUS OF RESIDENTS AND STAFF—Continued
[Thousands]

	Beginning of year 2021*	New during 2021	Total for 2021	Percent vaccinated by March 31	Number vaccinated by March 31	Remaining vaccination candidates 2021	New candidates 1st quarter 2022	Total first year candidates**
LTC Facility Staff	950	760	1,710	60	1,026	684	190	874
ICF–IID Residents	100	20	120	20	24	96	5	101
ICF–IID Staff	75	60	135	20	27	108	15	123
Total Persons	2,525	3,340	5,865	53	3,117	2,748	835	3,583
Residents Total	1,500	2,520	4,020	51	2,064	1,956	630	2,586
Staff Total	1,025	820	1,845	57	1,053	792	205	997
Total Persons	2,525	3,340	5,865	53	3,117	2,748	835	3,583
LTC Facility Total	2,350	3,260	5,610	55	3,066	2,544	815	3,359
ICF–IID Total	175	80	255	20	51	204	20	224
Total Persons	2,525	3,340	5,865	53	3,117	2,748	835	3,583

*Beginning of Year is roughly identical to average for year when population is stable.
**Estimated number potentially needing vaccination in the first full year after March 31st.

As presented in the third numeric column of Table 5, the total number of individuals either residing or working in all of these different facilities over the course of a year is about 5.9 million persons, which is more than twice the annual average number of residents or staff shown in the first numeric column. A new study, using data from detailed payroll records, found that median turnover rates for all nurse staff are approximately 90 percent a year.[78] Due to these high turnover rates, LTC facilities will require significantly more resident or staff vaccines compared to the total number of residents and staff in the facility at the beginning of the year. For example, when the Pharmacy Partnership completed its time commitment in LTC facilities, it probably had seen only about half of the persons who will reside or work in these facilities in 2021. Of course, most of these persons will have been vaccinated through other means when they enter the facilities during the remainder of 2021. That said, it is likely that there will be over one million residents and staff during the first year after this rule is published who will need vaccination. Much of the immediate need for LTC resident and staff education has already been accomplished through the Pharmacy Partnership for Long-Term Care Program. Even after the end of this program, remaining unvaccinated residents and staff will benefit from additional education, especially as additional information about vaccine safety and effectiveness is available. Some resident education can take place in group settings and some education will take place on a one-to-one level. What works best will depend on the circumstance of the resident and the best method for conveying the information and answering questions. Staff can use opportunities during normal day-to-day activities to educate the residents and their representatives (if they are present) on the immunization opportunities through the facility or its partners. Staff education, using CDC or FDA materials, can also take place in various formats and ways. Individualized counseling, resident meetings, staff meetings, posters, bulletin boards, and e-newsletters are all approaches that can be used to provide education. Informal education may also occur as staff go about their daily duties, and some who have been vaccinated may promote vaccination to others. Facilities may find that reward techniques, among other strategies, may help. In particular, the value of immunization as a crucial component of keeping residents healthy and well is already conveyed to staff in regard to influenza and pneumococcal vaccines. The COVID–19 vaccine education will build upon that knowledge.

The techniques for education and shared decision-making, where appropriate, are so numerous and varied that there is no simple way to estimate likely costs. Staff and resident hesitancy may and likely will change over time as the benefits of vaccination become clear to increasing numbers of participants in congregate settings. For purposes of estimation, we assume that, on average, 30 minutes of staff time will be devoted to education of each unvaccinated resident, resident representative, or staff person, at the same average hourly cost of $67.06 estimated for RNs in the Information Collection analysis. As for the recipients of such education, we assume that about three-fourths of them are residents, and one-fourth staff. We have little data on resident income but know that for most, Social Security or Supplemental Security Income are their principal sources of income.[79] For estimating purposes, we assume that their time is worth about $10.02 an hour (median income of older adults without earnings is $20,440 annually.[80] Since residents are rarely in the labor market while in the facility, this base income has not been adjusted for fringe benefits or employer expenses. For staff, we estimate hourly costs of $27.38 based on BLS data for healthcare support occupations (median of $13.69, doubled to account for fringe benefits and overhead).

We note that very little of this cost is likely to involve translation of documents, simply because very few documents are involved, and electronic and other assistance methods are so widespread. The vaccine information Fact Sheet required by FDA to be made available is already translated by FDA into the eight most common non-English languages in use in the United States and is downloadable online. (For the Moderna vaccine, for example, see *https://www.modernatx.com/covid19vaccine-eua/providers/language-resources*.) LanguageLine or similar services are always available on call if needed for an oral explanation of

[78] Ashvin Gandhi et al., ''High Nursing Staff Turnover In Nursing Homes Offers Important Quality Information,'' Health Affairs, March 2021, pages 384–391.

[79] Only about 13% have private sources of payment. See Jose Ness et al., ''Demographics and Payment Characteristics of Nursing Home Residents in the United States: A 23-Year Trend,'' Journal of Gerontology: MEDICAL SCIENCES, 2004, Vol. 59A, No. 11, pp. 1213–1217.

[80] Average income from Federal Reserve of St. Louis at *https://fred.stlouisfed.org/series/MEPAINUSA672N*.

a written document to someone who does not speak English. Many computer and phone applications (''Apps'') providing oral translations are available to assist those with language or vision problems, and hearing problems create no document translation requirements if a document in the reading language of that resident is available.[81]

If we assume that 20 percent of residents and clients in LTC facilities and ICFs–IID decline vaccination, taking account of both those offered and declining the vaccine before this rule takes effect and those offered it again in the first year, 930,000 additional vaccination counseling and education efforts would be made to residents (4,020,000 including 630,000 in the first quarter of 2022 for a total of 4,655,000 total individual residents × .2). This figure implicitly assumes that a much higher take-up rate was achieved during the first three months of 2021, likely about 80 to 90 percent of all those residents reached by Pharmacy Partners and other early vaccination efforts, and that there will be more and more varied effort needed for the remainder, most of whom presumably declined the initial offer. It also assumes that only about half of year-end residents will have been vaccinated when this rule is issued even though most residents at the beginning of the year will have been vaccinated. Hence, there will be about 517,000 residents needing vaccine education and offers needed to be made in the first full year (20 percent of rightmost Residents Total column of Table 5).

For education of staff, we make similar assumptions, except that early and anecdotal evidence suggests that a third or more are declining vaccination.[82] This means that about an additional 332,000 (one-third of 997,000) vaccination counseling and education efforts will need to be made to staff, including new hires, in the remainder of 2021 and the first quarter of 2022.

Taken together, these estimates for both residents and staff suggest that total counseling and education efforts would be made for perhaps 849,000 persons after the rule is issued, two-thirds residents and one-third staff. Some of those offers would be accepted and some declined (these figures do not include offers made to persons already vaccinated but do include those newly admitted to or hired by these facilities). Total cost of the educational efforts themselves would be approximately $28,442,000 (849,000 persons × .5 hours × $67 hourly cost). Cost of resident time to participate would be an additional $2,449,000 (849,000 persons × .667 × .5 hours × $8.65 hourly cost) and of staff time to participate an additional $1,631,000 (849,000 persons × .333 × .5 hours × $27.38 hourly costs). Second- and third-year totals would be lower, perhaps about three-fourths as much, taking into account both fewer remaining unvaccinated needing these efforts, and a sensible reduction in efforts aimed at persons who refuse to consider vaccination. Hence, total cost of these educational efforts to both educators and recipients would be a total of $35,220,000 in the first year and $26,415,000 in the second and third years.

The third major cost component is the vaccination, including both administration and the vaccine itself. We estimate that the average cost of a vaccination is what the Government pays under Medicare: $20 × 2 = $40 for two doses of a vaccine, and $20 × 2 for vaccine administration of two doses, for a total of $80 per resident. This estimate is made for simplicity, ignoring newer and one-dose vaccines, since the great majority of recipients are Medicare beneficiaries and we have no data yet on likely use of newer vaccines.[83] Assuming that the efforts to educate residents, clients, and staff succeed in raising the vaccinated percentage by 5 percent points over the course of the first year, calculated from the 70 percent (staff) to 80 percent (residents and clients) baseline likely to be achieved before this rule takes effect, total vaccination costs across these target groups resulting from this rule would be $23,460,000 ($80 × .05 × 5,865,000).

Finally, there is a cost category related to expenses not estimated as information collection costs because they meet an exception in the PRA for requirements that would be handled through ''usual and customary'' business practices. These exceptions are all discussed briefly in the ICR section of this preamble. Most of their costs are related mainly to recording in patient or personnel records for each resident and staff person that vaccine education, vaccine decision, and vaccinations for those accepting vaccination have all taken place. While there are large numbers of such record notations to be made, we estimate that they take only a few seconds per record. We have estimated that the added cost of these record-keeping functions as likely to be about 5 percent of all Information Collection costs.

All these aggregate costs can be converted to per person numbers since it is individual persons who are vaccinated. Dividing the estimated first year costs by an estimated 5.380 million people (4.02 million residents and 1.36 million workers) gives an average per resident or employee cost of $27.12 in the first year (159,056,000 divided by 5,865,000).

Another way to summarize these numbers is in terms of average cost per person newly vaccinated. Making the same assumption that about 5 percent of total persons (and 10 percent of those unvaccinated) would be newly vaccinated as a result of this rule, cost per person would be $542 ($27.12 divided by .05). Table 6 summarizes the overall cost estimates.

TABLE 6—ESTIMATE OF TOTAL COSTS

Cost category	Costs in first year	Costs in succeeding years
Developing NF Policies & Procedures	$38,360,000	$12,542,000
Developing Education Materials for Residents and Staff	4,181,000	NA
Keeping Vaccine Information Up-to-Date	6,271,000	6,271,000
Documentation Requirements	3,838,000	3,838,000

[81] Examples of translation Apps include Google Translate, iTranslate Voice 3, SayHi, TextGrabber, BrailleTranslater, and many more.

[82] The Kaiser Family Foundation estimates as of February 22 that to date 37 percent of all health care workers (not specific to LTC workers) have declined vaccination or decided to wait and see. See *https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccine-monitor/*.

[83] Vaccine and vaccination costs are generally paid by the Federal Government. What the Government pays varies from vaccine to vaccine, by when purchased and in what quantities, and varies by payer or provider. $40 per dose is a rough estimate based on experience to date. As is the case for all drugs, cost estimates also vary depending on research and development costs as well as manufacturing cost. These estimates do not reflect use of the new Johnson & Johnson/Jannsen one-dose vaccine. See the Healthline article at *https://www.healthline.com/health-news/how-much-will-it-cost-to-get-a-covid-19-vaccine*.

TABLE 6—ESTIMATE OF TOTAL COSTS—Continued

Cost category	Costs in first year	Costs in succeeding years
NHSN Reporting to CDC and CMS	27,175,000	27,175,000
Subtotal, NF Information Collection	79,825,000	49,826,000
ICF–IID Information Collection	11,426,000	5,351,000
Subtotal Information Collection	91,251,000	55,177,000
Educating Residents & Staff *	35,220,000	26,415,000
Providing Vaccine to Residents and Staff **	23,460,000	17,595,000
Keeping Records of the Above Activities	9,125,000	5,518,000
Total Costs	159,056,000	104,705,000

* These costs assume only unvaccinated are educated about vaccination.
** These costs assume about 5 percent of total persons accept the vaccine offer (over half already vaccinated).

While these estimates give the appearance of precision since they present costs to the nearest thousand dollars, this is simply the result of calculations based on numerical assumptions. There are major uncertainties in these estimates. One obvious example is whether vaccine efficacy will last more than the six months proven to date.[84] Presumably, re-vaccination each year could maintain a high level of protection if vaccine protection wore off in a year. Re-vaccination or use of new and improved vaccines would likely maintain the effectiveness of vaccination for residents and staff. But the estimated costs of this rule would change in the table column for succeeding years to a level roughly equal to the first year estimate even if re-vaccinations were to be necessary. For purposes of displaying the known second (and succeeding) year effects assuming no major changes in vaccine effectiveness, we have included in Table 5 (and the tables covering information collection costs) the predictable changes in second year cost estimates.

D. Anticipated Benefits of the Interim Final Rule

There will be over 5 million residents, clients, and staff each year in the LTC facilities and ICFs–IID covered by this rule. In our analysis of first-year benefits of this rule we focus on prevention of death among residents of LTC facilities and ICFs–IID, as well as on progress in reducing disease severity. We also focus only on benefits to the candidates for vaccination covered by this rule, not on possible benefits to family members, caregivers, or other persons who they might subsequently infect if not vaccinated.[85] Reductions in resident, client, and staff mortality are benefits for which techniques exist (though with some uncertainty) to express estimates in dollar terms. One of the major benefits of vaccination is that it lowers the cost of treating the disease among those who would otherwise be infected and have serious morbidity consequences. The largest part of those costs is for hospitalization and they are very substantial. As discussed later in the analysis we do have data on the average costs of hospitalization of these patients (it is, however, unclear as to how that cost is changing over time with better treatment options). A lesser but still very substantial amount of these morbidity costs is for care of gravely ill patients within the nursing home, but reducing those costs is another benefit we are unable to estimate at this time.

There is a potential offset to benefits that we have not estimated. As long as vaccine supplies do not meet all demands for vaccination, giving priority to some persons over others necessarily means that some persons will become infected who would not have been infected had the priorities been reversed. In this case, however, the priority for elderly persons (virtually all of whom have risk factors) who comprise the vast majority of LTC facility residents, is prioritizing those at higher risk of mortality and severe disease over those whose risk of death is multiple orders of magnitude lower.[86] As a result, there are some assumptions we make that could overstate benefits should the assumptions be overtaken by adverse events.

The HHS ''Guidelines for Regulatory Impact Analysis'' explain in some detail the concept of Quality Adjusted Life Years (QALYs).[87] QALYs, when multiplied by a monetary estimate such as the Value of a Statistical Life Year (VSLY), are estimates of the value that people are willing to pay for life-prolonging and life-improving health care interventions of any kind (see sections 3.2 and 3.3 of the HHS Guidelines for a detailed explanation). The QALY and VSLY amounts used in any estimate of overall benefits are not meant to be precise, but instead are rough statistical measures that allow an overall estimate of benefits expressed in dollars.

Under a common approach to benefit calculation, we can use a Value of a Statistical Life (VSL) to estimate the dollar value of the life-saving benefits of a policy intervention, such as this rule. We adopt the VSL of approximately $10.6 million in 2020 as described in the HHS Guidelines, adjusted for changes in real income and inflated to 2019 dollars using the Consumer Price Index. Assuming that the average rate of death from COVID–19 (following SARS–CoV–2 infection) at nursing home resident ages and conditions is 5 percent, and the average rate of death after vaccination is essentially zero, the expected value of each resident receiving the full course of two vaccines who would otherwise be infected with SARS–CoV–2 is about $530,000 ($10,600,000 × .05).

Under a second approach to benefit calculation, we can estimate the monetized value of extending the life of nursing home residents, which is based on expectations of life expectancy and the value per life-year. As explained in the HHS Guidelines, the average

[84] For a discussion of this issue, see Sumathi Reddy, ''How Long To Covid–19 Vaccines Protect You?'', The Wall Street Journal, April 13, 2021, at *https://www.wsj.com/articles/how-long-do-covid-19-vaccines-provide-immunity-11618258094.*

[85] We note that as of this writing there remains a major unanswered question as to whether and if so to what extent vaccinated persons transmit COVID–19.

[86] The risk of death from infection from an unvaccinated 75 to 84 year old person is 320 times more likely than the risk for an 18- to 29-years old person. CDC, ''Risk for COVID–19 Infection, Hospitalization, and Death by Age Group'', at *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html.*

[87] *https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis.*

individual in studies underlying the VSL estimates is approximately 40 years of age, allowing us to calculate a value per life-year of approximately $540,000 and $900,000 for 3 and 7 percent discount rates respectively. This estimate of a value per life-year corresponds to 1 year at perfect health. (These amounts might reasonably be halved for average nursing home residents, since non-institutionalized U.S. adults aged 80–89 years report average health-related quality of life (HRQL) scores of 0.753, and this figure is likely to be lower for nursing home residents.) [88] Assuming that the average life expectancy of long-term care residents is five years, the monetized benefits of saving one statistical life would be about $2.5 million ($540,000 × annually for 5 years) at a 3 percent discount rate and about $3.7 million ($900,000 × annually for 5 years) at a 7 percent discount rate. Assuming that the average rate of death from COVID–19 (SARS-CoV–2 infection) at nursing home resident ages and conditions is 5 percent, and the average rate of death after vaccination is essentially zero, the expected life-extending value of each resident receiving the full course of two vaccines who would otherwise be infected is $125 thousand at a 3 percent discount rate and $185 thousand at a 7 percent discount rate. A similar calculation can be made for staff, who will gain many more years of life but whose risk of death is far smaller since their age distribution is so much younger. Yet another calculation for clients of ICFs–IID would also result in many more years of life but far smaller risks of death since their age distribution is typically far younger than that of LTC residents. It is difficult to ascertain the number of ICF–IID clients that would be infected without vaccination. Deaths from COVID–19 in unvaccinated LTC residents to date are about 130,000, or close to one tenth of the average LTC resident census of 1.4 million, a huge contrast to the handful of deaths in the vaccination results from Israel.[89] We do not have sufficient data so as to accurately estimate annual resident inflows and outflows over time, but it is clear that several hundred thousand new individuals each year make the total number served during the year far higher than point in time or average counts (see Table 5).

We do know that large numbers of residents or staff were vaccinated through the Pharmacy Partnership, which for nursing home residents relied most heavily on the CVS and Walgreens drug store chains. In its latest report, the Partnership reported that to date it had vaccinated about 2.2 million residents in long-term care facilities, although fewer than two thirds of these had received two doses.[90] We do know that significant fractions of staff, perhaps one-third or more, have to date declined vaccination when offered.[91] Progress has been very substantial, but many remain unvaccinated among both residents and staff. This interim final rule has significant potential to support further vaccinations as vaccination opportunities from other sources expand.

The preceding calculations address residential long-term care. Long-term residents are a major group within nursing homes and are generally in the nursing home because their needs are more substantial and they need assistance with the activities of daily living, such as cooking, bathing, and dressing. These long-term stays are primarily funded by the Medicaid program (also, through long-term care insurance or self-financed), and the residential care services these residents receive are not normally covered by Medicare or any other health insurance. A second major group within the same facilities receives short-term skilled nursing care services. These services are rehabilitative and generally last only days, weeks, or months. They usually follow a hospital stay and are primarily funded by the Medicare program or other health insurance. The importance of these distinctions is that the numbers of residents in each category are different. The average number of persons in facilities for long-term care over the course of a year is about 1.2 million residents (as is the point-in-time number), and the total number of persons over the course of a year is about 1.6 million. The average number in skilled nursing care over a year is about 200,000 million persons, but the average length of stay is weeks rather than years.[92] The annual turnover in this group is such that about 2.3 million residents are served each year. There is some overlap between these two populations and the same person may be admitted on more than one occasion. For purposes of this analysis (although we have no documented basis for estimating those numbers), we assume that the expected longevity for each group is identical on average, and that a total of 3.9 million persons are served each year. We further assume that 20 percent of these are new residents each year who must be offered vaccination (most are already vaccinated, as discussed later in the analysis).

These nursing facilities have about 950,000 full-time equivalent employees. For these persons, the average age is about 50, which creates two offsetting effects: They have more years of life expectancy than residents, but their risk of from COVID–19 death is far lower. For purposes of this analysis, we assume that the vaccination is effective for at least one year, and use a one-year period as our primary framework for calculation of potential benefits, not as a specific prediction but as a likely scenario that avoids forecasting major and unexpected changes that are either strongly adverse or strongly beneficial. If we were adding up totals for benefits we would assume that the risk of death after COVID–19 infection is likely only one-half of one percent (one tenth of the resident rate) or less for the unvaccinated members of this group, reflecting the far lower mortality rates for persons who are mostly in the 30 to 65 year old age ranges compared to the far older residents.[93] We assume that the total number of individual employees is 50 percent higher than the full-time equivalent but that only half that number are primarily employed at only one nursing facility, two offsetting assumptions about the number of employees working at each facility (many employees are part-time consultants or the equivalent who serve multiple nursing facilities on a part-time basis). We further assume that employee turnover is 80 percent a year, lower than the results for nurses previously cited. Accordingly, we estimate that 80

[88] Hanmer, J. W.F. Lawrence, J.P. Anderson, R.M. Kaplan, D.G. Fryback. 2006. ''Report of Nationally Representative Values for the Noninstitutionalized US Adult Population for 7 Health-Related Quality-of-Life Scores.'' *Medical Decision Making.* 26(4): 391–400.

[89] Deaths are from COVID–19 Nursing Home Data, CMS, Week Ending 2/21/2021, at *https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/.*

[90] See *https://www.cdc.gov/vaccines/covid-19/planning/index.html.*

[91] See the discussion and data in the CDC report ''Early COVID–19 First-Dose Vaccination Coverage Among Residents and Staff Members of Skilled Nursing Facilities Participating in the Pharmacy Partnership for Long-Term Care Program—United States, December 2020–January 2021,'' at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7005e2.htm?s_cid=mm7005e2_x.*

[92] In fact, the average length of stay for skilled nursing care is about 25 days. See MEDPAC, Report to the Congress: Medicare Payment Policy, March 2019, ''Skilled nursing facility services,'' page 200.

[93] See the previously cited CDC report on risks by age group. In the age intervals used by CDC, the 40–49 year old group is in the middle of typical employment age ranges. The risk of death in this age group is one tenth that of those aged 65–74. We emphasize with round numbers that nothing about these data are fixed and unlikely to change (*e.g.,* as better future treatments are used to treat severe cases).

percent of 950,000, or 760,000, are new employees each year and must be offered vaccination (again, most are already vaccinated), for a total of 1,710,000 eligible employees over the course of a year.

As for ICFs–IID, there are about 6,000 facilities, serving about 100,000 people at any one time, an average of about 15 people per facility.[94] The age profile of these clients is similar to that of the adult population at large. Turnover rates are unknown, but likely to be substantial because these clients have many alternatives. We estimate 80 percent a year for turnover, the same as for nursing facilities. The costs and benefits of COVID–19 vaccination services for this group are roughly comparable to those of nursing home staff. There do not appear to be data on number of staff at these facilities, but based on the nature of the services provided it appears likely that the staff to client ratio is similar to that in other congregate settings (group homes, assisted living facilities), and likely to be about three-fourths of the client population, or about 75,000 full-time equivalent staff, with similar turnover patterns as well. Adding 80 percent to allow for staff turnover, gives a total of 135,000 staff candidates for vaccination.

We have some data on the costs of treating serious illness among the unvaccinated who become infected, are hospitalized, and survive. Among those age 65 years or above, or with severe risk factors, as many as 40 percent of those known to be infected required hospitalization in the first month of the pandemic. Among adults age 21 years to 64 years, about 10 percent of those infected required hospitalization.[95] For our estimates, we assume a 20 percent hospitalization rate among people aged 65 years or older in nursing homes, reflecting both that their conditions are significantly worse than those of similarly aged adults living independently, and that pre-hospitalization treatments have improved. Of the LTC facility and ICF–IID candidates for vaccination in the first year covered by this rule, about three-fourths are age 65 years or above. Hence, the age-weighted hospitalization rate that we project is about 16 percent. Among those hospitalized at any age, the average cost is about $20,000.[96]

To put these cost, benefit, and volume numbers in perspective, vaccinating one hundred previously unvaccinated LTC residents who would otherwise become infected with SARS–CoV–2 and have a COVID–19 illness would cost approximately $54,200 ($542 × 100) in paperwork, education, and vaccination costs. Using the VSL approach to estimation would produce life-saving benefits of about $2,650,000 for these 100 people ($530,000 × 100 × .05), again assuming the death rate for those ill from COVID–19 of this age and condition is one in twenty. Reductions in health care costs from hospitalization would produce another $320,000 ($20,000 × 100 × .16) in benefits for this group assuming that 16% would otherwise be hospitalized. However, this comparison is should be taken as necessarily hypothetical and contingent due to the analytic, data, and uncertainty challenges discussed throughout this regulatory impact assessment. As the discussion of other patient groups covered by this rule demonstrates, they present similar if not identical magnitudes of both costs and benefits for affected individuals (benefits from staff vaccinations, however, are far lower). Consequently, the primary medium- to long-run benefit-cost issue is not the general magnitude of likely effects on those who get vaccinated as a result of the rule, but the difficult questions of estimating (1) likely numbers of individuals in both client and staff categories who are likely to be unvaccinated when the rule goes into effect and (2) to be willing to accept vaccination in the coming months and years.[97]

Of particular importance is that the vaccination rates and raw numbers of people vaccinated take into account that in total only about half of those who will be residents and clients in these facilities at some time during the year have already been residents or clients during the months served by the Pharmacy Partnership effort. For example, our estimated vaccination rate as of March 31, 2021, for LTC residents assumes that about 90 percent of the residents in January through March will have been vaccinated. But given the turnover expected during the rest of the year, only about 70 percent of the annual total will have been vaccinated by the end of 2021, or by the end of the first year including the first quarter of 2022. As a result, about 3.6 million persons will be vaccination candidates subject to this rule over the first year. Some of these persons may have been vaccinated elsewhere, but the facilities regulated under this rule will need to query each incoming resident and it is likely that as many as a third of these will be candidates for COVID–19 vaccination. A major caution about these estimates: None of the sources of enrollment information for these programs regularly collect and publish information on client or staff turnover during the course of a year. The estimates here are based on inferences from scattered data on average length of stay, mortality, job vacancies, news accounts, and other sources that by happenstance are available for one type of facility or type of resident or another. Nor do we have data on the number of persons in these settings who will be vaccinated through other means during the remainder of the year.

There are also dimensions of positive and negative benefits in the medium- to long-run that we have not been able to estimate. For example, there is insufficient evidence as to whether the current or reasonably foreseeable vaccines will maintain their protective efficacy for more than six months.

Until very recently, demand for COVID–19 vaccination has exceeded supply throughout the U.S.[98] Especially in previous months, vaccination distribution policies giving priority to various groups (for example, aged, health care workers, and other essential services workers) has meant that those given priority have benefited to some extent at the expense of those in lower priorities. Regardless of priorities, we know that younger persons are much less likely to experience hospitalization or death after infection. For example, the risk of death among infected persons age 65 to 74 years is ten times greater

[94] By far the largest source of data related to ICF and other IID services is ''In-Home and Residential Long-Term Supports and Services for Persons with Intellectual or Developmental Disabilities: Status and Trends 2017'', at *https://ici-s.umn.edu/files/aCHyYaFjMi/risp_2017*.

[95] There are few data sources for this statistic and, thus, it may be out of date. See MMWR, ''Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019—United States, February 12–March 28, 2020'', April 3, 2020, at *https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e2.htm#T2_down*.

[96] This is not a robust estimate, but is supported by several sources. See for example Jiangzhuo Chen et al., ''Medical costs of keeping the US economy open during COVID–19,'' Scientific Reports, *Nature.com*, July 19 2020, at *https://pubmed.ncbi.nlm.nih.gov/32743613/*, and Michel Kohli et al., ''The potential public health and economic value of a hypothetical COVID–19 vaccine in the United States: Use of cost-effectiveness modeling to inform vaccination prioritization,'' Science Direct, February 12, 2021, at *https://pubmed.ncbi.nlm.nih.gov/33483216/*.

[97] For a survey of the evidence on this issue, see Gillian K. Steelfisher et al., ''An Uncertain Public—Encouraging Acceptance of Covid-19 Vaccines,'' The New England Journal of Medicine, March 3, 2021.

[98] The shortage issue has now largely been addressed, as is well illustrated in the recent removal of age restrictions designed to give highest priority in using limited vaccine supplies to the elderly and health care workers. See, for example, news stories: *https://www.abc27.com/news/health/coronavirus/official-biden-moving-vaccine-eligibility-date-to-april-19/*.

than the risk of death among infected persons age 40 to 49 years. Yet the average years of remaining life among younger persons at these ages is far greater than among older persons at higher ages. Age, however, is not anywhere near a perfect indicator of risk since, for example, health care workers and those with immune system disorders face elevated risks from exposure. Sorting out all these factors to reach either a qualitative or quantitative estimate of net benefits from any particular policy is extremely complex and is one reason why vaccination priorities have differed among the states and over time.

All these data and estimation limitations apply to even the short-term impacts of this rule, and major uncertainties remain as to the future course of the pandemic, including but not limited to vaccine effectiveness in preventing disease transmission from those vaccinated, and the long-term effectiveness of vaccination.

E. Other Effects

1. Sources of Payment

We anticipate that virtually all of the costs of this rule will be reimbursed from funds already appropriated under the CARES Act and the American Rescue Plan Act of 2021. For example, the amounts provided in the Provider Relief Fund is $7.4 billion, many times more than the relatively small costs of this rule. As previously discussed, if there are treatment cost savings to hospitals and other care providers as a result of the vaccinations that will be made due to this rule, the treatment cost savings would in turn result in savings to payers. It is likely that half or more of these savings would primarily accrue to Medicare given the elderly or disability status of most clients and Medicare's role as primary payer, but there would also be substantial savings to Medicaid, private insurance paid by employers and employees, and private out-of-pocket payers including residents.

2. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. Under the RFA, ''small entities'' include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. For purposes of the RFA, we estimate that many LTC facilities and most ICFs–IID are small entities as that term is used in the RFA because they are either nonprofit organizations or meet the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). HHS uses an increase in costs or decrease in revenues of more than 3 to 5 percent as its measure of ''significant economic impact.'' The HHS standard for ''substantial number'' is 5 percent or more of those that will be significantly impacted, but never fewer than 20.

The average annual cost of a nursing home stay is about $271.98 per day or about $100,000 per year.[99] As estimated previously, the average annual cost of this rule is about $24.70 per resident or staff person in the first year. This cost does not approach the 3 percent threshold. For ICFs–IID, one estimate of average annual costs per client is $140,000, also a level at which this rule does not approach the 3 percent threshold.[100] Moreover, since most or all of these costs will be reimbursed through the CARES Act or other COVID–19 funding sources, the financial strain on these facilities should be negligible and the likely net effect positive. Considering the cost savings from treating seriously ill residents, the financial impact is likely to be positive. Therefore, the Department has determined that this interim final rule will not have a significant economic impact on a substantial number of small entities and that a final RIA is not required. Finally, this IFC was not preceded by a general notice of proposed rulemaking and the RFA requirement for a final regulatory flexibility analysis does not apply to final rules not preceded by a proposed rule.

3. Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a RIA if a proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. For purposes of this requirement, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Because this rule has no direct effects on any hospitals, the Department has determined that this interim final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. This interim final rule is also exempt because that provision of law only applies to final rules for which a proposed rule was published.

4. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates will impose spending costs on state, local, or tribal governments, or by the private sector, require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This rule does contain mandates on private sector entities, and we estimate the resulting amount to be about the same as this threshold in the first year. This IFC was not preceded by a notice of proposed rulemaking, and therefore the requirements of UMRA do not apply. The information in this RIA and the preamble as a whole would, however, meet the requirements of UMRA.

5. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Nothing in this rule will have a substantial direct effect on state or local governments, preempt state laws, or otherwise have federalism implications.

F. Alternatives Considered

As discussed earlier in the preamble, a major substantive alternative that we considered was to require vaccination activities (education and offering) for all persons who may provide paid or unpaid services, such as visiting specialists or volunteers, who are not on the regular payroll on a weekly or more frequent basis. That is, individuals who work in the facility infrequently. We also considered including visitors, such as family members. All these categories present major problems for compliance, enforcement, and record-keeping, as well as a multitude of complexities related to visit frequency, resident exposure, and vaccination management. Furthermore, the efficacy of such a policy would be difficult to establish. For example, vaccinating a one-time visitor on the day of their visit would not improve resident safety because the vaccine is not instantly effective upon administration. There are also ethical

[99] See Marcum Accountants & Advisors, A Five Year Nursing Home Statistical Analysis (2014 to 2018), at *https://www.marcumllp.com/wp-content/uploads/marcum-five-year-nursing-home-statistical-analysis-2014-2018.pdf.*

[100] See In-Home and Residential Long-Term Supports and Services for Persons with Intellectual or Developmental Disabilities: Status and Trends 2017, op cit, page 77.

issues related to potential discouragement of visiting volunteers or family members. Instead, we believe that such decisions are best left to each facility, in consideration of CMS and CDC guidance. Our expectation is that vaccination of regular visitors in any of these categories will be encouraged, whether or not the vaccinations are offered by the facility itself.

G. Accounting Statement and Table

The Accounting Table summarizes the quantified impact of this rule. It covers only one year because there will likely be many developments regarding treatments and vaccinations and their effects in future years and we have no way of knowing which will most likely occur. A longer period would be even more speculative than the current estimates.

As explained in various places within the RIA and the preamble as a whole, there are major uncertainties as to the effects of COVID–19 on nursing and other congregate living facilities as well as the nation at large. For example, the duration of vaccine effectiveness in preventing infection, reducing disease severity, reducing the risk of death, and preventing disease transmission by those vaccinated are all currently unknown. These uncertainties also impinge on benefits estimates. For those reasons we have not quantified into annual totals either the life-extending or medical cost-reducing benefits of this rule, and have used only a one-year projection for the cost estimates in our Accounting Statement (our estimates are for the last nine months of 2021 and the first three months of 2022). We welcome comments on all of our assumptions and welcome any additional information that would narrow the ranges of uncertainty.

TABLE 7—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS

[$ Millions]

Category	Primary estimate	Lower bound	Upper bound	Units		
				Year dollars	Discount rate (%)	Period covered
Benefits: Lives Extended (not annualized or monetized).	.....	.....	.....	2020	7	First year.
Reduced Medical Expenditures (not annualized or monetized).	.....	.....	.....	2020	3	First year.
Costs: Annualized Monetized ($ million/year).	159	119	199	2020	7	First year.
	159	119	199	2020	3	First year.
Cost Notes: Administrative costs from increased efforts to vaccinate residents and staff.						
Transfers	None.					

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

I, Elizabeth Richter, Acting Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 22, 2021.

List of Subjects in 42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 483 as set forth below:

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 1. The authority citation for part 483 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r.

■ 2. Section 483.80 is amended by—

■ a. Revising the heading for paragraph (d);

■ b. Adding paragraph (d)(3);

■ c. Removing the word ''and'' at the end of paragraph (g)(1)(vii);

■ d. Revising paragraph (g)(1)(viii); and

■ e. Adding paragraph (g)(1)(ix).

The revisions and additions read as follows:

§ 483.80 Infection control.

* * * * *

(d) *Influenza, pneumococcal, and COVID–19 immunizations*— * * *

(3) *COVID–19 immunizations.* The LTC facility must develop and implement policies and procedures to ensure all the following:

(i) When COVID–19 vaccine is available to the facility, each resident and staff member is offered the COVID–19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized;

(ii) Before offering COVID–19 vaccine, all staff members are provided with education regarding the benefits and risks and potential side effects associated with the vaccine;

(iii) Before offering COVID–19 vaccine, each resident or the resident representative receives education regarding the benefits and risks and potential side effects associated with the COVID–19 vaccine;

(iv) In situations where COVID–19 vaccination requires multiple doses, the resident, resident representative, or staff member is provided with current information regarding those additional doses, including any changes in the benefits or risks and potential side effects associated with the COVID–19 vaccine, before requesting consent for administration of any additional doses;

(v) The resident, resident representative, or staff member has the opportunity to accept or refuse a COVID–19 vaccine, and change their decision;

(vi) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident representative was provided education regarding the benefits and potential risks associated with COVID–19 vaccine; and

(B) Each dose of COVID–19 vaccine administered to the resident; or

(C) If the resident did not receive the COVID–19 vaccine due to medical contraindications or refusal; and

(vii) The facility maintains documentation related to staff COVID–19 vaccination that includes at a minimum, the following:

(A) That staff were provided education regarding the benefits and potential risks associated with COVID–19 vaccine;

(B) Staff were offered the COVID–19 vaccine or information on obtaining COVID–19 vaccine; and

(C) The COVID–19 vaccine status of staff and related information as indicated by the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN).

* * * * *

(g) * * *

(1) * * *

(viii) The COVID–19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID–19 vaccine received, and COVID–19 vaccination adverse events; and

(ix) Therapeutics administered to residents for treatment of COVID–19.

* * * * *

■ 3. Section 483.430 is amended by adding paragraph (f) to read as follows:

§ 483.430 Condition of participation: Facility staffing.

* * * * *

(f) *Standard: COVID–19 vaccines.* The facility maintains documentation related to staff that includes at a minimum, all of the following:

(1) Staff were provided education regarding the benefits and risks and potential side effects associated with the COVID–19 vaccine.

(2) Staff were offered COVID–19 vaccine or information on obtaining the COVID–19 vaccine.

■ 4. Section 483.460 is amended by redesignating paragraph (a)(4) as paragraph (a)(5) and adding new paragraph (a)(4) to read as follows:

§ 483.460 Conditions of participation: Health care services.

(a) * * *

(4) The intermediate care facility for individuals with intellectual disabilities (ICF/IID) must develop and implement policies and procedures to ensure all of the following:

(i) When COVID–19 vaccine is available to the facility, each client and staff member is offered the COVID–19 vaccine unless the immunization is medically contraindicated or the client or staff member has already been immunized.

(ii) Before offering COVID–19 vaccine, all staff members are provided with education regarding the benefits and risks and potential side effects associated with the vaccine.

(iii) Before offering COVID–19 vaccine, each client or the client's representative receives education regarding the benefits and risks and potential side effects associated with the COVID–19 vaccine.

(iv) In situations where COVID–19 vaccination requires multiple doses, the client, client's representative, or staff member is provided with current information regarding each additional dose, including any changes in the benefits or risks and potential side effects associated with the COVID–19 vaccine, before requesting consent for administration of each additional doses.

(v) The client, client's representative, or staff member has the opportunity to accept or refuse COVID–19 vaccine, and change their decision.

(vi) The client's medical record includes documentation that indicates, at a minimum, the following:

(A) That the client or client's representative was provided education regarding the benefits and risks and potential side effects of COVID–19 vaccine; and

(B) Each dose of COVID–19 vaccine administered to the client; or

(C) If the client did not receive the COVID–19 vaccine due to medical contraindications or refusal.

* * * * *

Dated: May 10, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–10122 Filed 5–11–21; 11:15 am]

BILLING CODE 4120–01–P

Exhibit 6

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MONTANA, MISSOULA DIVISION

MONTANA MEDICAL ASSOCIATION, ET. AL., *Plaintiffs,* and MONTANA NURSES ASSOCIATION, *Plaintiff-Intervenors*, v. AUSTIN KNUDSEN, ET AL., DEFENDANTS.	No. CV-21-108-M-DWM **EXPERT REPORT OF DR. JAYANTA BHATTACHARYA**

EXPERT REPORT OF DR. JAYANTA BHATTACHARYA

EXPERIENCE & CREDENTIALS

1. I am a former Professor of Medicine and current Professor of Health Policy at Stanford University School of Medicine and a research associate at the National Bureau of Economic Research. I am also the Director of Stanford's Center for Demography and Economics of Health and Aging. I hold an M.D. and Ph.D. from Stanford University. I have published 160 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. My research has been cited in the peer-reviewed scientific literature more than 13,300 times. My curriculum vitae is attached to this declaration as Exhibit A.

2. I have dedicated my professional career to analyzing health policy, including infectious disease epidemiology and policy, and the safety and efficacy of medical interventions. I have studied extensively and commented publicly on the necessity and safety of vaccine requirements for those who have contracted and recovered from COVID-19 (individuals who have "recovered immunity,"

sometimes called "natural immunity"). I am familiar with the emergent scientific and medical literature on this topic and pertinent government policy responses to the issue both in the United States and abroad.

3. My assessment of vaccine immunity is based on studies on the efficacy and safety of the two vaccines to receive full approval from the Food and Drug Administration (FDA) and the one vaccine for which the FDA has granted Emergency Use Authorization (EUA) for use in the United States. These include two mRNA-technology vaccines (manufactured by Pfizer-BioNTech and Moderna) and an adenovirus-vector vaccine technology (manufactured by Johnson & Johnson). Of those, the Pfizer vaccine, also known as Comirnaty, and Moderna vaccine have full FDA approval.

4. I have been asked to provide my opinion on several matters related to the use of one of the COVID-19 vaccines above:

- Based on current medical and scientific knowledge, the risk SARS-CoV-2 virus poses to different population groups;
- Whether, based on the current medical and scientific

knowledge, vaccines effectively protect against infection (and therefore disease spread);

- Whether, based on the current medical and scientific knowledge, immunity after COVID recovery is categorically inferior to vaccine immunity to prevent reinfection and transmission of the SARS-CoV-2 virus;
- Whether, based on the existing medical and scientific understanding of SARS-CoV-2 transmission and recovery, there is any categorical distinction between recovered immunity and vaccine immunity;
- Whether there is scientific evidence to support the notion that immunity provided by COVID recovery should not be considered as a reason to be excused from a vaccine mandate;
- Whether, based on the current medical and scientific knowledge, Omicron presents a grave danger to the population; and

- Whether, based on the current medical and scientific knowledge, vaccines are effective at preventing Omicron infections.
- Whether, based on the current medical and scientific knowledge, healthcare staff and the public's vaccination status affects the spread and transmission of COVID-19 within healthcare settings.

5. I can summarize my opinions briefly. The scientific evidence strongly indicates that for the vast majority of children and young adults, COVID-19 infection poses less mortality risk than seasonal influenza; while the COVID vaccines are effective at protecting vaccinated individuals against severe disease, they provide only short-lasting and limited protection versus infection and disease transmission; the recovery from COVID disease provides strong and lasting protection against severe disease (hospitalization or death) if reinfected, at least as good and likely better than the protection offered by the COVID vaccines; requiring vaccines for COVID recovered patients, thus, provides only a limited benefit while exposing them to the risks associated with the

vaccination; Omicron does not present a grave danger to most of the population; and vaccines are ineffective at preventing Omicron infections.

6. I have not and will not receive any financial or other compensation to prepare this report or to testify in this case. Nor have I received compensation for preparing declarations or reports or for testifying in *any* other case related to the COVID-19 pandemic or any personal or research funding from any pharmaceutical company. My participation here has been motivated solely by my commitment to public health, just as my involvement in other cases has been.

OPINIONS

I. COVID-19 Infection Fatality Risk

7. SARS-CoV-2, the virus that causes COVID-19 infection, entered human circulation in 2019 in China. The virus itself is a member of the coronavirus family of viruses, several of which cause typically mild respiratory symptoms upon infection in humans. The SARS-CoV-2 virus, by contrast, induces a wide range of clinical responses upon infection. These presentations range from entirely

asymptomatic infection to mild upper respiratory disease with unusual symptoms like loss of sense of taste and smell, hypoxia, or a deadly viral pneumonia that is the primary cause of death due to SARS-CoV-2 infection.

8. The mortality danger from COVID-19 infection varies substantially by age and a few chronic disease indicators.[1] For most of the population, including the vast majority of children and young adults, COVID-19 infection poses less mortality risk than seasonal influenza. By contrast, for older people – especially those with severe comorbid chronic conditions – COVID-19 infection poses a high infection fatality risk, on the order of 5%.

9. The best evidence on the infection fatality rate from SARS-CoV-12 infection (that is, the fraction of infected people who die due to the infection) comes from seroprevalence studies. The definition of seroprevalence of COVID-19 is the fraction of people in a population who have specific antibodies against SARS-CoV-2 in

[1] Public Health England (2020) Disparities in the Risk and Outcomes of COVID-19. August 2020. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/908434/Disparities_in_the_risk_and_outcomes_of_COVID_August_2020_update.pdf

their bloodstream. A seroprevalence study measures the fraction of a population with antibodies produced specifically by people infected by the SARS-CoV-2 virus. Specific antibodies in blood provide excellent evidence that an individual was previously infected.

10. Seroprevalence studies provide better evidence on the total number of people who have been infected than do case reports or positive reverse transcriptase-polymerase chain reaction (RT-PCR) test counts. PCR tests are the most common test used to check whether a person currently has the virus or viral fragments in their body (typically in the nasopharynx). The PCR test should not be used to count the total number of people infected to date in a population. Case reports and PCR test counts both miss infected people who are not identified by the public health authorities or who do not volunteer for RT-PCR testing. That is, they miss people who were infected but recovered from the condition without coming to the attention of public health authorities. Because they ignore unreported infections, fatality rate estimates based on case reports

or positive test counts are substantially biased toward reporting a higher fatality rate.

11. According to a meta-analysis[2] by Dr. John Ioannidis of every seroprevalence study conducted to date of publication with a supporting scientific paper (74 estimates from 61 studies and 51 different localities worldwide), the median infection survival rate—the inverse of the infection fatality rate—from COVID-19 infection is 99.77%. For COVID-19 patients under 70, the meta-analysis finds an infection survival rate of 99.95%. A separate meta-analysis[3] by other scientists independent of Dr. Ioannidis' group reaches qualitatively similar conclusions.

12. A study of the seroprevalence of COVID-19 in Geneva, Switzerland (published in *The Lancet*)[4] provides a detailed age

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[2] John P.A. Ioannidis , *The Infection Fatality Rate of COVID- 19 Inferred from Seroprevalence Data*, Bulletin of the World Health Organization BLT 20.265892.

[3] Andrew T. Levin, et al., *Assessing the Age Specificity of Infection Fatality Rate for COVID- 19: Meta-Analysis & Public Policy Implications* (Aug. 14, 2020) MEDRXIV, http://bit.ly/3gplolV.

[4] Silvia Stringhini, et al., *Seroprevalence of Anti-SARS-CoV-2 lgG Antibodies in Geneva, Switzerland (SEROCoV-POP): A Population Based Study* (June 11, 2020) THE LANCET, https://bit.ly/3187S13.

breakdown of the infection survival rate in a preprint companion paper:[5] 99.9984% for patients 5 to 9 years old; 99.99968% for patients 10 to 19 years old; 99.991% for patients 20 to 49 years old; 99.86% for patients 50 to 64 years old; and 94.6% for patients above 65.

13. I estimated the age-specific infection fatality rates from the Santa Clara County seroprevalence study[6] data (for which I am the senior investigator). The infection survival rate is 100% among people between 0 and 19 years (there were no deaths in Santa Clara in that age range up to that date); 99.987% for people between 20 and 39 years; 99.84% for people between 40 and 69 years; and 98.7% for people above 70 years.

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[5] Francisco Perez-Saez, et al. *Serology- Informed Estimates of SARS-COV-2 Infection Fatality Risk in Geneva, Switzerland* (June 15,2020) OSF PREPRINTS, http://osf.io/wdbpe/

[6] Eran Bendavid, et al., *COVID- 19 Antibody Seroprevalence in Santa Clara County, California* (April 30,2020) INT J EPIDEMIOL. 2021 May 17;50(2):410-419. doi: 10.1093/ije/dyab010. PMID: 33615345; PMCID: PMC7928865. https://pubmed.ncbi.nlm.nih.gov/33615345/

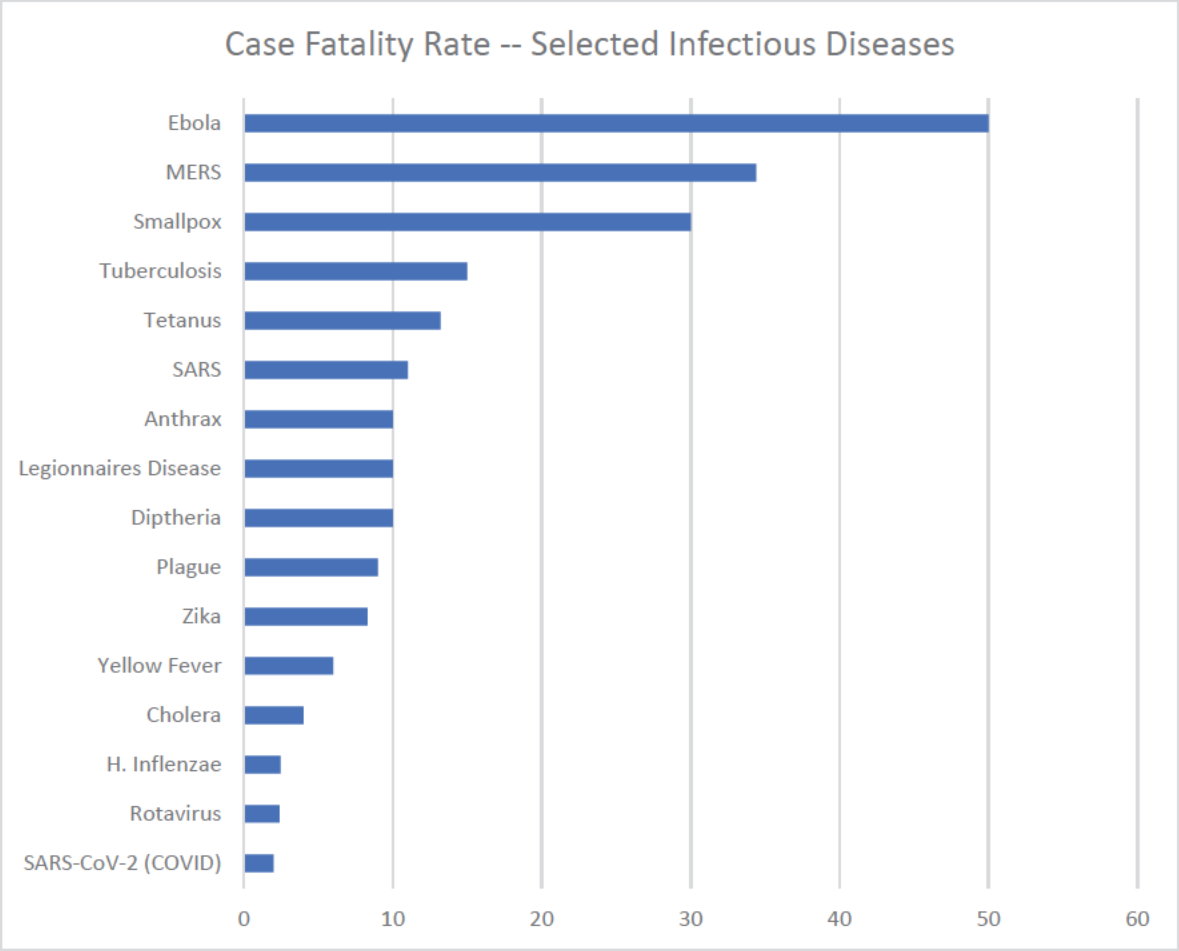
14. Those numbers are consistent with what the US CDC has reported. A US CDC report[7] found between 6 and 24 times more SARS-CoV-2 infections than cases reported between March and May 2020. Correspondingly, the CDC's estimate of the infection fatality rate for people ages 0-19 years is 0.003%, meaning infected children have a 99.997% survivability rate. For people ages 20-49 years, it was 0.02%, meaning that young adults have a 99.98% survivability rate. For people ages 50-69 years, it was 0.5%, meaning this age group has a 99.5% survivability rate. Finally, for people ages 70+ years, it was 5.4%, meaning seniors have a 94.6% survivability rate.[8] There is, thus, no substantial qualitative disagreement about the infection fatality rate reported by the CDC and other sources in the scientific literature. This should come as no surprise since they all rely on seroprevalence studies to estimate infection fatality rates. All of these mortality rate estimates are

[7] Fiona P. Havers, et al., *Seroprevalence of Antibodies to SARS-CoV-2 in 10 Sites in the United States, March 23-May 12, 2020* (Jul. 21, 2020) JAMA INTERN MED., https://bit.ly/3goZUgy.

[8] COVID- 19 Pandemic Planning Scenarios, Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html.

derived from data before the emergence of the Omicron variant, which has caused lower mortality per infection than previous variants.

15. It is helpful to provide some context for how large the mortality risk COVID infection poses relative to the risk posed by other infectious diseases. Since seroprevalence-based mortality estimates are not readily available for every disease, I plot case fatality rates in the figure immediately below, defined as the number of deaths due to the disease divided by the number of identified or diagnosed cases of that disease. The case fatality rate for SARS-CoV-2 is ~2% (though that number has decreased with the availability of vaccines and effective treatments). By contrast, the case fatality rate for SARS is over five times higher than that, and for MERS, it is 16 times higher.



16. Perhaps the most important implication of these estimates is that they identify two distinct populations of people who face a very different risk from COVID infection. One segment – the elderly and others with severe chronic disease – faces a higher mortality risk if infected (especially if unvaccinated and not COVID recovered). A second segment – typically non-elderly people – faces a low mortality risk if infected. Instead, it faces much greater harm from lockdowns, school closures, and other non-pharmaceutical

interventions than COVID infection. The right strategy, then, is focused protection of the vulnerable population by prioritizing them for vaccination while lifting lockdowns and other restrictions on activities for the rest since they cause harm without corresponding benefit for the non-vulnerable. The Great Barrington Declaration, of which I am a primary co-author, describes an alternate policy of focused protection. This policy would lead to fewer COVID-related deaths and fewer non-COVID-related deaths than universal lockdowns or a strategy that lets the virus rip through the population. My co-authors of this Declaration include Prof. Martin Kulldorff of Harvard University and Prof. Sunetra Gupta of Oxford University. Over 15,000 epidemiologists and public health professionals and 50,000 medical professionals have co-signed the Declaration.[9]

II. Recovered immunity Provides Durable Protection Against Reinfection and Against Severe Outcomes If Reinfected; COVID-19 Vaccines Provide Limited Protection Against Infection but Durable Protection Against Severe Outcomes if Infected.

[9] Bhattacharya J, Gupta S, Kulldorff M (2020) Great Barrington Declaration. https://gbdeclaration.org

17. Both vaccine-mediated immunity and recovered immunity provide extensive protection against severe disease from subsequent SARS-CoV-2 infection. There is no reason to presume, however, that vaccine immunity offers a higher level of protection than recovered immunity. Since vaccines arrived one year after the disease, there is stronger evidence for long-lasting immunity from recovered immunity than from the vaccines.

18. Both types of immunity are based on the same basic immunological mechanism—stimulating the immune system to generate an antibody response. In clinical trials, the efficacy of those vaccines was initially tested by comparing the antibody levels in the blood of vaccinated individuals to those who had recovered immunity. Later Phase III studies of the vaccines established 94%+ clinical efficacy of the mRNA vaccines against symptomatic COVID

illness.[10] [11] A Phase III trial showed 85% efficacy for the Johnson & Johnson adenovirus-based vaccine against symptomatic disease.[12]

19. Immunologists have identified many immunological mechanisms of immune protection after recovery from infections. Studies have demonstrated prolonged immunity with respect to

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[10] Baden, L. R., El Sahly, H. M., Essink, B., Kotloff, K., Frey, S., Novak, R., Diemert, D., Spector, S. A., Rouphael, N., Creech, C. B., McGettigan, J., Khetan, S., Segall, N., Solis, J., Brosz, A., Fierro, C., Schwartz, H., Neuzil, K., Corey, L., Zaks, T. for the COVE Study Group (2021). Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *The New England Journal of Medicine*, *384*(5), 403-416. doi: 10.1056/NEJMoa2035389

[11] Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Moreira, E. D., Zerbini, C., Bailey, R., Swanson, K. A., Roychoudhury, S., Koury, K., Li, P., Kalina, W. V., Cooper, D., Frenck, R. W. Jr., Hammitt, L. L., Gruber, W. C. (2020). Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *The New England Journal of Medicine*, *387*(27), 2603-2615. doi: 10.1056/NEJMoa2034577

[12] Sadoff, J., Gray, G., Vandebosch, A., Cárdenas, V., Shukarev, G., Grinsztejn, B., Goepfert, P. A., Truyers, C., Fennema, H., Spiessens, B., Offergeld, K., Scheper, G., Taylor, K. L., Robb, M. L., Treanor, J., Barouch, D. H., Stoddard, J., Ryser, M. F., Marovich, M. A., Douoguih, M. for the ENSEMBLE Study Group. (2021). Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. *The New England Journal of Medicine*, *384*(23), 2187-2201. doi: 10.1056/NEJMoa2101544

memory T and B cells,[13] bone marrow plasma cells,[14] spike-specific neutralizing antibodies,[15] and IgG+ memory B cells[16] following naturally-acquired immunity.

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[13] Dan, J. M., Mateus, J., Kato, Y., Hastie, K. M., Yu, E. D., Faliti, C. E., Grifoni, A., Ramirez, S. I., Haupt, S., Frazier, A., Nakao, C., Rayaprolu, V., Rawlings, S. A., Peters, B., Krammer, F., Simon, V., Saphire, E. O., Smith, D. M., Weiskopf, D., Crotty, S. (2021). Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. *Science*, *371*, 1-13. doi: 10.1126/science.abf4063 (finding that memory T and B cells were present up to eight months after infection, noting that "durable immunity against secondary COVID-19 disease is a possibility in most individuals").

[14] Turner, J. S., Kim, W., Kalaidina, E., Goss, C. W., Rauseo, A. M., Schmitz, A. J., Hansen, L., Haile, A., Klebert, M. K., Pusic, I., O'Halloran, J. A., Presti, R. M. & Ellebedy, A. H. (2021). SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans. *Nature*, *595*(7867), 421-425. doi: 10.1038/s41586-021-03647-4 (study analyzing bone marrow plasma cells of recovered COVID-19 patients reported durable evidence of antibodies for at least 11 months after infection, describing "robust antigen-specific, long-lived humoral immune response in humans"); Callaway, E. (2021, May 26). Had COVID? You'll probably make antibodies for a lifetime. *Nature*. https://www.nature.com/articles/d41586-021-01442-9#:~:text=Many%20people%20who%20have%20been,recovered%20from%20COVID%2D191 ("The study provides evidence that immunity triggered by SARS-CoV-2 infection will be extraordinarily long-lasting" and "people who recover from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades").

20. Multiple extensive, peer-reviewed studies comparing natural and vaccine immunity have now been published. These studies overwhelmingly conclude that recovered immunity provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (Pfizer and Moderna).

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[15] Ripperger, T. J., Uhrlaub, J. E., Watanabe, M., Wong, R., Castaneda, Y., Pizzato, H. A., Thompson, M. R., Bradshaw, C., Weinkauf, C. C., Bime, C., Erickson, H. L., Knox, K., Bixby, B., Parthasarathy, S., Chaudhary, S., Natt, B., Cristan, E., El Aini, T., Rischard, F., Bhattacharya, D. (2020). Orthogonal SARS-CoV-2 serological assays enable surveillance of low-prevalence communities and reveal durable humor immunity. *Immunity*, *53*(5), 925-933. doi: 10.1016/j.immuni.2020.10.004 (study finding that spike and neutralizing antibodies remained detectable 5-7 months after recovering from infection).

[16] Cohen, K. W., Linderman, S. L., Moodie, Z., Czartoski, J., Lai, L., Mantus, G., Norwood, C., Nyhoff, L. E., Edara, V. V., Floyd, K., De Rosa, S. C., Ahmed, H., Whaley, R., Patel, S. N., Prigmore, B., Lemos, M. P., Davis, C. W., Furth, S., O'Keefe, J., McElrath, M. J. (2021). Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells. *medRxiv*, Preprint. (study of 254 recovered COVID patients over 8 months "found a predominant broad-based immune memory response" and "sustained IgG+ memory B cell response, which bodes well for rapid antibody response upon virus re-exposure." "Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients").

21. Specifically, studies confirm the efficacy of recovered immunity against reinfection of COVID-19[17] and show that the vast

[17] Shrestha, N. K., Burke, P. C., Nowacki, A. S., Terpeluk, P. & Gordon, S. M. (2021). Necessity of COVID-19 vaccination in previously infected individuals. *medRxiv*, Preprint. doi: 10.1101/2021.06.01.21258176 ("not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study" and concluded that those with recovered immunity are "unlikely to benefit from COVID-19 vaccination"); Perez, G., Banon, T., Gazit, S., Moshe, S. B., Wortsman, J., Grupel, D., Peretz, A., Tov, A. B., Chodick, G., Mizrahi-Reuveni, M., & Patalon, T. (2021). A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: A preliminary report. *medRxiv*, Preprint. doi: 10.1101/2021.03.06.21253051 (Israeli study finding that approximately 1/1000 of participants were reinfected); Bertollini, R., Chemaitelly, H., Yassine, H. M., Al-Thani, M. H., Al-Khal, A., & Abu-Raddad, L. J. (2021). Associations of vaccination and of prior infection with positive PCR test results for SARS-CoV-2 in airline passengers arriving in Qatar. *JAMA*, *326*(2), 185-188. doi: 10.1001/jama.2021.9970 (study of international airline passengers arriving in Qatar found no statistically significant difference in risk of reinfection between those who had been vaccinated and those who had previously been infected); Pilz, S., Chakeri, A., Ioannidis, J. P. A., Richter, L., Theiler-Schwetz, V., Trummer, C., Krause, R., Allerberger, F. (2021). SARS-CoV-2 re-infection risk in Austria. *European Journal of Clinical Investigation*, *51*(4), 1-7. doi: 10.1111/eci.13520 (previous SARS-CoV-2 infection reduced the odds of re-infection by 91% compared to first infection in the remaining general population); Breathnach, A. S., Duncan, C. J. A., El Bouzidi, K., Hanrath, A. T., Payne, B. A. I., Randell, P. A., Habibi, M. S., Riley, P. A., Planche, T. D., Busby, J. S., Sudhanva, M., Pallett, S. J. C. & Kelleher, W. P. (2021). Prior COVID-19

majority of reinfections are less severe than first-time infections.[18]

For example, an Israeli study of approximately 6.4 million

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protects against reinfection, even in the absence of detectable antibodies. *The Journal of Infection*, *83*(2), 237-279. doi: 10.1016/j.jinf.2021.05.024 (0.86% of previously infected population in London became reinfected); Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total $CD4^+$ and $CD8^+$ T cell reactivity in infected or vaccinated individuals, *Cell Reports Medicine 2*(7), 100355 (an examination of the comparative efficacy of T cell responses to existing variants from patients with recovered immunity compared to those who received an mRNA vaccine found that the T cell responses of both recovered COVID patients and vaccines were effective at neutralizing mutations found in SARS-CoV-2 variants).

[18] Abu-Raddad, L. J., Chemaitelly, H., Coyle, P., Malek, J. A., Ahmed, A. A., Mohamoud, Y. A., Younuskunju, S., Ayoub, H. H., Kanaani, Z. A., Kuwari, E. A., Butt, A. A., Jeremijenko, A., Kaleeckal, A. H., Latif, A. N., Shaik, R. M., Rahim, H. F. A., Nasrallah, G. K., Yassine, H. M., Al Kuwari, M. G., Al Romaihi, H. E., Al-Thani, M. H., Al Khal, A., Bertollini, R. (2021). SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy. *EClinicalMedicine*, *35*, 1-12. doi: 10.1016/j.eclinm.2021.100861 (finding that of 129 reinfections from a cohort of 43,044, only one reinfection was severe, two were moderate, and none were critical or fatal); Hall, V. J., Foulkes, S., Charlett, A., Atti, A., Monk, E. J. M., Simmons, R., Wellington, E., Cole, M. J., Saei, A., Oguti, B., Munro, K., Wallace, S., Kirwan, P. D., Shroti, M., Vusirikala, A., Rokadiya, S., Kall, M., Zambon, M., Ramsay, M., Hopkins, S. (2021). SARS-CoV-2 infection rates of

individuals demonstrated that recovered immunity provided equivalent if not better protection than vaccine immunity in preventing COVID-19 infection, morbidity, and mortality.[19] Of the 187,549 unvaccinated persons with recovered immunity in the study, only 894 (0.48%) were reinfected; 38 (0.02%) were hospitalized, and 16 (0.008%) were hospitalized with severe disease, and only one died, an individual over 80 years of age. Another study analyzing data from Italy found that only 0.31% of

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antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study. *The Lancet*, *397*(10283), 1459-1469. doi: 10.1016/S0140-6736(21)00675-9 (finding "a 93% lower risk of COVID-19 symptomatic infection… [which] show[s] equal or higher protection from natural infection, both for symptomatic and asymptomatic infection"); Hanrath, A. T., Payne, B., A., I., & Duncan, C. J. A. (2021). Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection. *The Journal of Infection*, *82*(4), e29-e30. doi: 10.1016/j.jinf.2020.12.023 (examined reinfection rates in a cohort of healthcare workers and found "no symptomatic reinfections" among those examined and that protection lasted for at least 6 months).

[19] Goldberg, Y., Mandel, M., Woodbridge, Y., Fluss, R., Novikov, I., Yaari, R., Ziv, A., Freedman, L., & Huppert, A. (2021). Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2. vaccine protection: A three-month nationwide experience from Israel. *medRxiv*, Preprint. doi: 10.1101/2021.04.20.21255670

COVID-recovered patients experienced reinfection within a year after the initial infection.[20]

22. Before the emergence of the Omicron variant, variants did not escape the immunity against infection provided by prior infection or vaccination.[21] [22] In a study of a large population of patients in Israel, *vaccinated* people who had not been previously infected had 13 times higher odds of experiencing a breakthrough infection with the Delta variant than patients who had recovered

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[20] Vitale, J., Mumoli, N., Clerici, P., de Paschale, M., Evangelista, I., Cei, M. & Mazzone, A. (2021). Assessment of SARS-CoV-2 reinfection 1 year after primary infection in a population in Lombardy, Italy. *JAMA Internal Medicine*, *181*(10), 1407-1409. doi: 10.1001/jamainternmed.2021.2959

[21] Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total $CD4^+$ and $CD8^+$ T cell reactivity in infected or vaccinated individuals, *Cell Reports Medicine 2,* 100355.

[22] Wu, K., Werner, A. P., Moliva, J. I., Koch, M., Choi, A., Stewart-Jones, G. B. E., Bennett, H., Boyoglu-Barnum, S., Shi, W., Graham, B. S., Carfi, A., Corbett, K. S., Seder, R. A. & Edwards, D. K. (2021). mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants. *bioRxiv*, Preprint. doi: 10.1101/2021.01.25.427948

from COVID but were never vaccinated.[23] They had 27 times higher odds of experiencing subsequent symptomatic COVID disease and seven times higher odds of hospitalization. The design of this Israeli study was particularly strong – it tracked large cohorts of people over time from the time of vaccination or initial infection and thus carefully distinguished the effect of time since initial exposure or vaccination in estimating its effect estimates. This is important because both vaccine-mediated and infection-mediated protection against subsequent infection diminish with time.

23. In summary, the overwhelming conclusion of the pertinent scientific literature is that recovered immunity is at least as effective against subsequent reinfection as even the most effective vaccines.

24. In contrast to the concrete findings regarding the robust durability of recovered immunity, the immunity provided by

[23] Gazit, S., Shlezinger, R., Perez, G., Lotan, R., Peretz, A., Ben-Tov, A., Cohen, D., Muhsen, K., Chodick, G. & Patalon, T. (2021). Comparing SARS-CoV-2 recovered immunity to vaccine-induced immunity: Reinfections versus breakthrough infections. *medRxiv*, Preprint. doi: 10.1101/2021.08.24.21262415

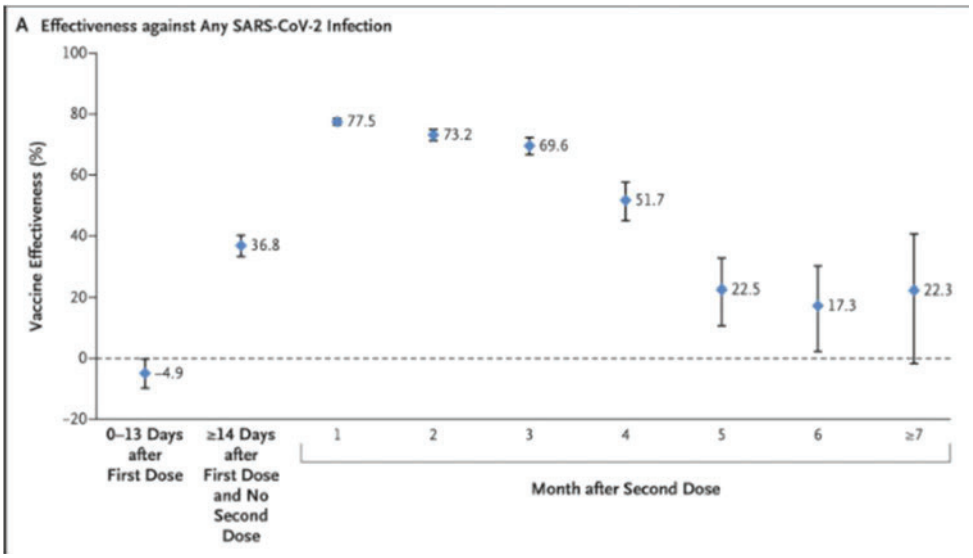
vaccination against infection appears to be short-lived, especially in the Omicron era.

25. A study from Qatar by Chemaitelly and colleagues (recently published in the New England Journal of Medicine), which tracked 927,321 individuals for six months after vaccination, concluded that the Pfizer vaccine's "induced protection against infection appears to wane rapidly after its peak right after the second dose, but it persists at a robust level against hospitalization and death for at least six months following the second dose."[24]

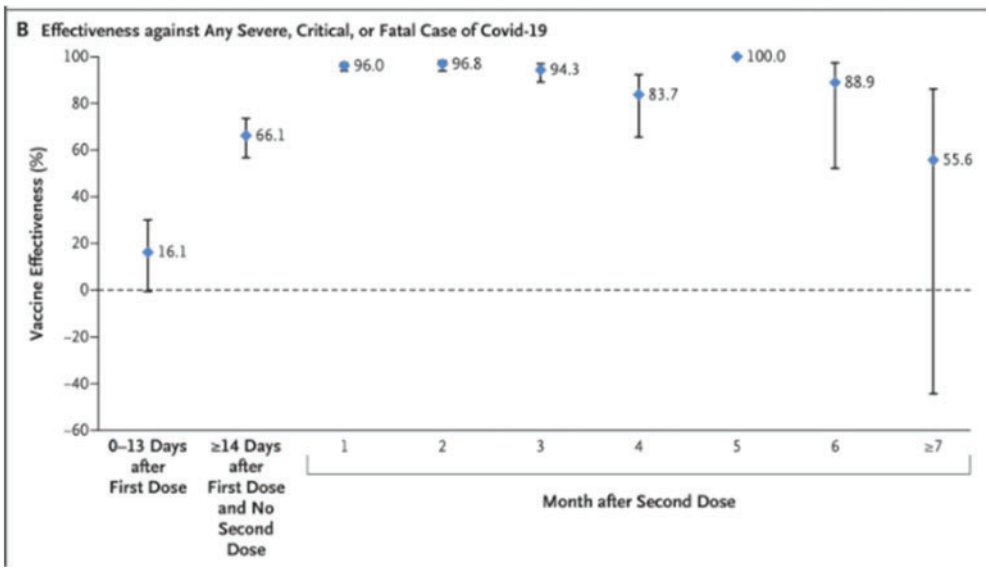
26. The key figures from the Qatari study are reproduced immediately below. Panel A shows that vaccine-mediated protection against infection peaks at 77.5% one month after the second dose, and then declines to 22.5%, five months after the second dose. According to this result, vaccines effectively protect

[24] Chemaitelly H, Tang P, Hasan MR, AlMukdad S, Yassine HM, Benslimane FM, Al Khatib HA, Coyle P, Ayoub HH, Al Kanaani Z, Al Kuwari E, Jeremijenko A, Kaleeckal AH, Latif AN, Shaik RM, Abdul Rahim HF, Nasrallah GK, Al Kuwari MG, Al Romaihi HE, Butt AA, Al-Thani MH, Al Khal A, Bertollini R, Abu-Raddad LJ. Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar. N Engl J Med. 2021 Oct 6:NEJMoa2114114. doi: 10.1056/NEJMoa2114114. Epub ahead of print. PMID: 34614327; PMCID: PMC8522799.

against infection (and therefore disease spread) for a short period of time after the second dose of the mRNA vaccines.



27. On the other hand, Panel B shows that protection versus severe disease is long lasting after vaccination—even though the person will no longer be fully protected against infection and, presumably, disease spread. At six months after the second dose, the vaccine remains 88.9% efficacious versus severe disease. While it appears to dip at seven months to 55.6% efficacy, the confidence interval is so wide that it is consistent with no decrease whatsoever even after seven months.



28. The Qatari study is no outlier. A large study in California tracked the infection rates for nearly 5 million patients vaccinated with two doses of the Pfizer mRNA vaccine. The study tracked both SARS-CoV-2 infections as well as COVID-19 related hospitalizations. The figure immediately below plots the trend in vaccine efficacy over time for different age groups in the population cohort. **Panel A** on the right plots effectiveness versus SARS-CoV-2 *infections*.[25] Though the drop in effectiveness is not as steep as in

[25] Tartof SY, Slezak JM, Fischer H, Hong V, Ackerson BK, Ranasinghe ON, Frankland TB, Ogun OA, Zamparo JM, Gray S, Valluri SR, Pan K, Angulo FJ, Jodar L, McLaughlin JM. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6

the Qatari study, there is, nevertheless, a sharp drop. While in the first month, vaccine effectiveness is near 90% for all age-groups, by month 5, it drops to nearly 50% for all the groups. By contrast, **Panel B** plots vaccine efficacy versus *hospitalizations*. It remains high with no decline over time –near 90% throughout the period. The vaccine provides durable private protection versus severe disease, but declining protection versus infection (and hence transmission).

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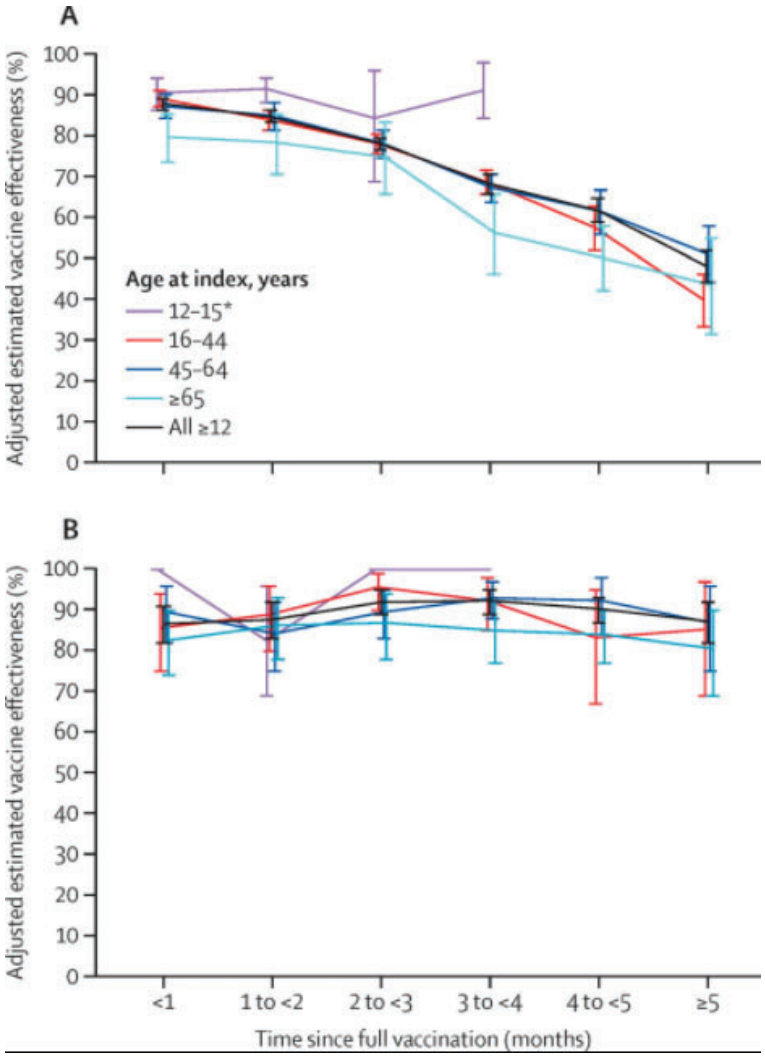
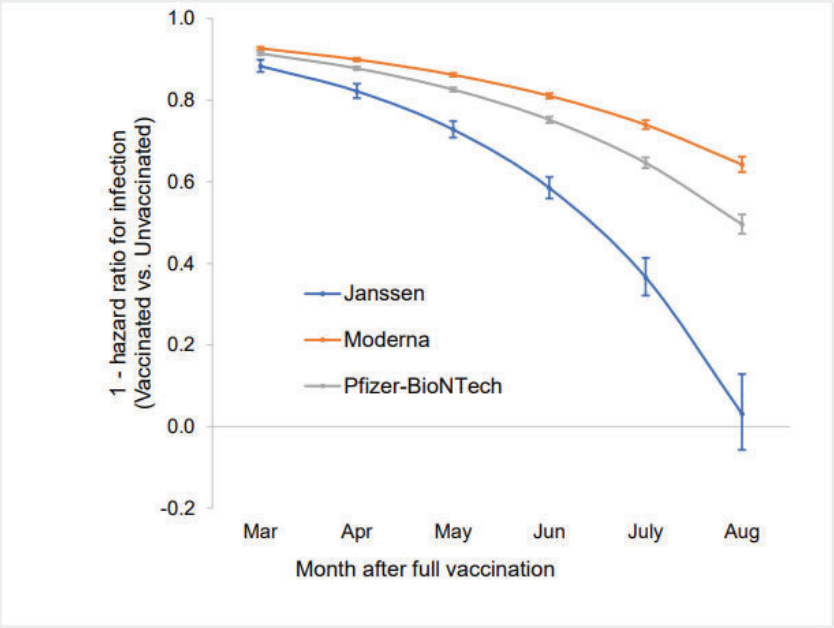
months in a large integrated health system in the USA: a retrospective cohort study. *Lancet*. 2021 Oct 16;398(10309):1407-1416. doi: 10.1016/S0140-6736(21)02183-8. Epub 2021 Oct 4. PMID: 34619098; PMCID: PMC8489881.



29. Another recent study tracked 620,000 vaccinated U.S. veterans to measure breakthrough infections for the three vaccines in common use in the U.S.[26] Like the other studies, the authors of the study found a sharp decline in vaccine effectiveness versus infection. Five months after vaccination, the effectiveness of the

[26] Cohn BA, Cirillo PM, Murphy CC, et al. Breakthrough SARS-CoV-2 Infections in 620,000 U.S. Veterans, February 1, 2021 to August 13, 2021. medRxiv. October 14, 2021. https://doi.org/10.1101/2021.10.13.21264966;

J&J vaccine dropped from ~90% to less than 10%; the Pfizer vaccine dropped from ~90% to ~50%; and the Moderna dropped from ~90%



to ~65%. The figure on this page tracks the decline in effectiveness of the vaccines against infection over time documented in this study. This study corroborates yet another study that documented declining vaccine efficacy in the first three months after vaccination against disease transmission in the era of the Delta variant.[27]

30. Yet another study conducted in Wisconsin confirmed that vaccinated individuals can shed infectious SARS-CoV-2 viral

[27] Eyre, D. W., Taylor, D., Purver, M., Chapman, D., Fowler, T., Pouwels, K. B., Walker, A. S. & Peto, T. E. A. (2021). The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. *medRxiv*, Preprint. doi: 10.1101/2021.09.28.21264260

particles.[28] The authors analyzed nasopharyngeal samples to check whether patients showed evidence of infectious viral particles. They found that vaccinated individuals were at least as likely as unvaccinated individuals to be shedding live virus. They concluded:

> Combined with other studies these data indicate that vaccinated and unvaccinated individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-2 is frequently found even in vaccinated persons.

31. A study in the U.K. during its wave of delta COVID cases compared the likelihood of a vaccinated individual passing on the disease to someone within their same household relative to unvaccinated patients.[29] This study tracked these groups of patients over time to the point they tested positive for COVID. At

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[28] Riemersma, K. K., Grogan, B. E., Kita-Yarbro, A., Halfmann, P. J., Segaloff, H. E., Kocharian, A., Florek, K. R., Westergaard, R., Bateman, A., Jeppson, G. E., Kawaoka, Y., O'Connor, D. H., Friedrich, T. C., & Grande, K. M. (2021). Shedding of infectious SARS-CoV-2 despite vaccination. *medRxiv*, Preprint. doi: 10.1101/2021.07.31.21261387

[29] Singanayagam A, Hakki S, Dunning J, et al. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study [published online ahead of print, 2021 Oct 29]. Lancet Infect Dis. 2021;doi:10.1016/S1473-3099(21)00648-4

that point, study investigators measured levels of the SARS-CoV-2 virus in the patients, and observed whether the patients passed on the disease to other household members. The authors find that while vaccination does reduce the fraction of time that a patient passes the disease on to household members from 38% [95% confidence interval: 24-53] to 25% [95% confidence interval: 18-33], there was no statistically significant difference (p=0.17). They conclude:

> Vaccination reduces the risk of delta variant infection and accelerates viral clearance. Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts.

32. The CDC recognizes the importance of recovered immunity in its updated science brief analyzing the difference in immunity from infection-induced and vaccine-induced immunity.[30] The CDC noted that "confirmed SARS-CoV-2 infection decreased risk of subsequent infection by 80–93% for at least 6–9 months,"

[30] CDC, Science Brief: SARS-CoV-2 Infection-Induced and Vaccine-Induced Immunity (updated Oct. 29, 2021), https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html#anchor_1635539757101

with some studies showing "slightly higher protective effects (89-93%)." It also noted that "researchers have predicted that the immune response following infection would continue to provide at least 50% protection against reinfection for 1–2 years following initial infection with SARS-CoV-2 or vaccination. This would be similar to what is observed with seasonal coronaviruses."

33. The CDC science brief does claim that vaccine-induced immunity is stronger than immunity from natural infection.[31] The study the CDC relies on to support this claim is not determinative, however, for several reasons.[32] First, its result is contrary to the weight of other evidence, as set forth above. Second, the study compared hospitalization of those infected—and had recovered immunity—90-225 days after their infection while against those who had completed their RNA vaccine regime 45-213 days before reinfection. Because immunity—regardless of how gained—wanes

[31] *Id.*

[32] Bozio CH, Grannis SJ, Naleway AL, et al. Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19–Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity — Nine States, January–September 2021. MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021.

over time, the failure to adequately compare like periods means that the study's conclusions are biased in favor of vaccine-induced immunity. Indeed, the study admits this weakness. Third, the study design itself does not permit it to address the critical question of interest – whether COVID-recovery without vaccination or vaccination without COVID-recovery provides stronger protection against COVID-related hospitalization. The study analyzes only patients who are already in the hospital. To obtain an accurate answer to the question of interest, it would need to include and analyze patients before entering the hospital. As it is, the study implicitly and incorrectly assumes that the set of hospitalized patients with COVID-like symptoms is representative of the population at large, which is untrue.

34. In summary, the evidence to date strongly suggests that, while vaccines—like recovered immunity—protect against severe disease, they, unlike recovered immunity, provide only short-lasting protection against subsequent infection and disease spread. In short, there is no medical or scientific reason to believe

that vaccine immunity will prove longer-lasting immunity than recovered immunity, much less more durable immunity.

35. The United States government is an outlier relative to other developed countries in its refusal to recognize the efficacy of recovered immunity. For instance, the Netherlands recently extended the duration of its "recovered immunity certificate," which can be used in lieu of a vaccine passport from 180 days to 365 days.[33] A similar exemption was made for recovered immunity in vaccine passports in the U.K. when the country required them.[34]

III. OMICRON DOES NOT PRESENT A GRAVE DANGER

36. The Omicron variant now represents substantially all new SARS-COV2 infections in the United States. This fact renders any remaining basis for a vaccine mandate obsolete.

37. An analysis from the South African government's National Institute for Communicable Diseases provides reason for

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[33] Block J. Vaccinating people who have had covid-19: why doesn't recovered immunity count in the US? BMJ. 2021 Sep 13;374:n2101. doi: 10.1136/bmj.n2101. Erratum in: BMJ. 2021 Sep 15;374:n2272. PMID: 34518194.

[34] Diver T. Vaccine passports will show 'recovered immunity' for people who have had Covid. MSN News. June 6, 2021.

optimism: S-Gene Target Failure (presumptive Omicron) cases are 80% less likely to be hospitalized.[35]

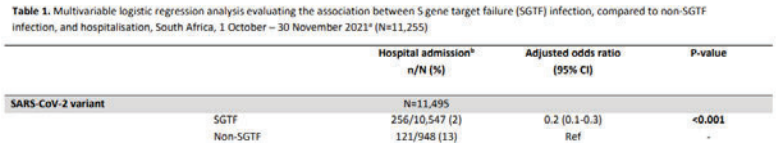


Table 1. Multivariable logistic regression analysis evaluating the association between S gene target failure (SGTF) infection, compared to non-SGTF infection, and hospitalisation, South Africa, 1 October – 30 November 2021[a] (N=11,255)

		Hospital admission[b] n/N (%)	Adjusted odds ratio (95% CI)	P-value
SARS-CoV-2 variant		N=11,495		
	SGTF	256/10,547 (2)	0.2 (0.1-0.3)	<0.001
	Non-SGTF	121/948 (13)	Ref	-

38. Data from Scotland also strongly suggests the same optimistic conclusion: "early national data suggest that Omicron is associated with a two-thirds reduction in the risk of COVID-19 hospitalisation when compared to Delta."[36]

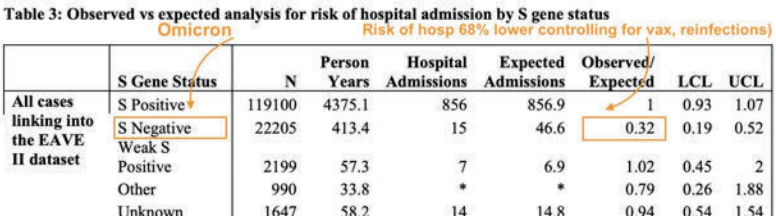


Table 3: Observed vs expected analysis for risk of hospital admission by S gene status

Omicron

Risk of hosp 68% lower controlling for vax, reinfections)

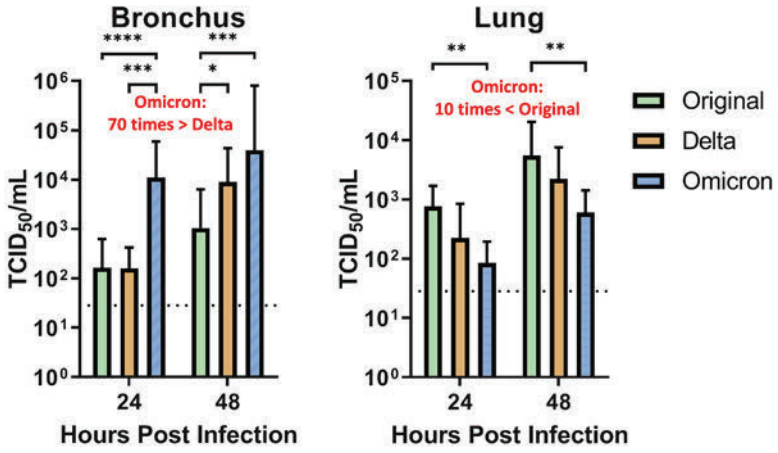
	S Gene Status	N	Person Years	Hospital Admissions	Expected Admissions	Observed/ Expected	LCL	UCL
All cases linking into the EAVE II dataset	S Positive	119100	4375.1	856	856.9	1	0.93	1.07
	S Negative	22205	413.4	15	46.6	0.32	0.19	0.52
	Weak S Positive	2199	57.3	7	6.9	1.02	0.45	2
	Other	990	33.8	*	*	0.79	0.26	1.88
	Unknown	1647	58.2	14	14.8	0.94	0.54	1.54

35 https://www.medrxiv.org/content/10.1101/2021.12.21.21268116v1.full.pdf

36 https://www.research.ed.ac.uk/en/publications/severity-of-omicron-variant-of-concern-and-vaccine-effectiveness-

39. Denmark's data shows Omicron cases were three times less likely to end up with hospital admissions than the previous dominant variant, Delta.[37]

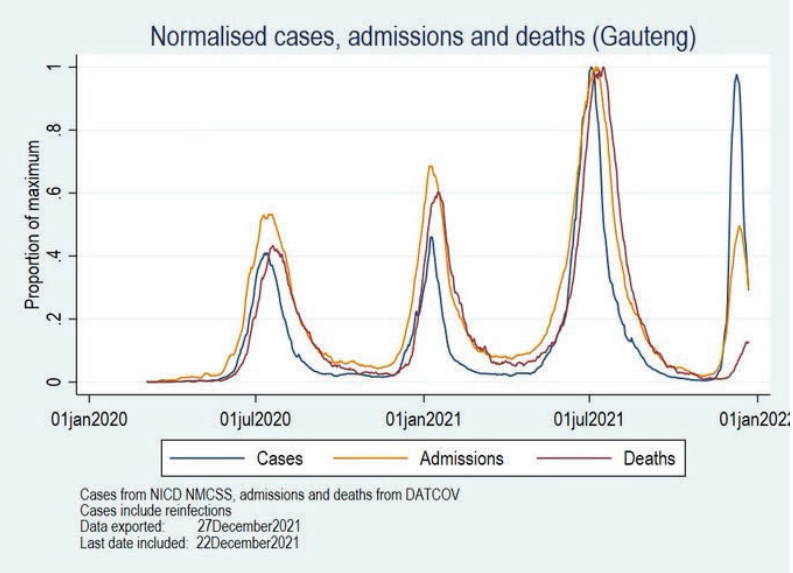
40. Hong Kong University researchers pointed to the likely reason, or mechanism, for Omicron's increased infectiousness but reduced virulence: it replicates far more efficiently in the bronchus and upper respiratory tract than Delta, but less efficiently in the lungs:[38]



[37] https://arstechnica.com/science/2021/12/omicron-cases-less-likely-to-require-hospital-treatment-studies-show/

[38] http://www.med.hku.hk/en/news/press/20211215-omicron-sars-cov-2-infection

41. Compelling evidence of Omicron ending any grave danger from SARS-CoV2 comes from South Africa, particularly the Gauteng province (population 18 million) where the first recognized Omicron wave occurred. According to Dr. Harry Moultrie of the South African government's National Institute for Communicable Diseases, Gauteng cases peaked on December 9 at 97 percent of the delta wave. Even more reassuringly, deaths were only 13 percent of the delta peak:[39]



42. A recently published working paper by a South African team of scientists who were conducting a sero-epidemiological

[39] https://twitter.com/hivepi/status/1475383429403484163

survey in the Gautang Province confirms the conclusion that Omicron infection is substantially less likely to require hospitalization or induce mortality than infection with other strains. While cases may rise sharply as a wave of Omicron sweeps through a region, hospitalizations and deaths do not follow. The authors conclude:[40]

> "We demonstrate widespread underlying SARS-CoV-2 seropositivity in Gauteng Province prior to the current Omicron-dominant wave, with epidemiological data showing an uncoupling of hospitalization and death rates from infection rate during Omicron circulation."

43. Based on their Omicron experience, some South African scientists have effectively declared the pandemic over, stating:[41]

> "All indicators suggest the country may have passed the peak of the fourth wave at a national level… While the Omicron variant is highly transmissible, there has

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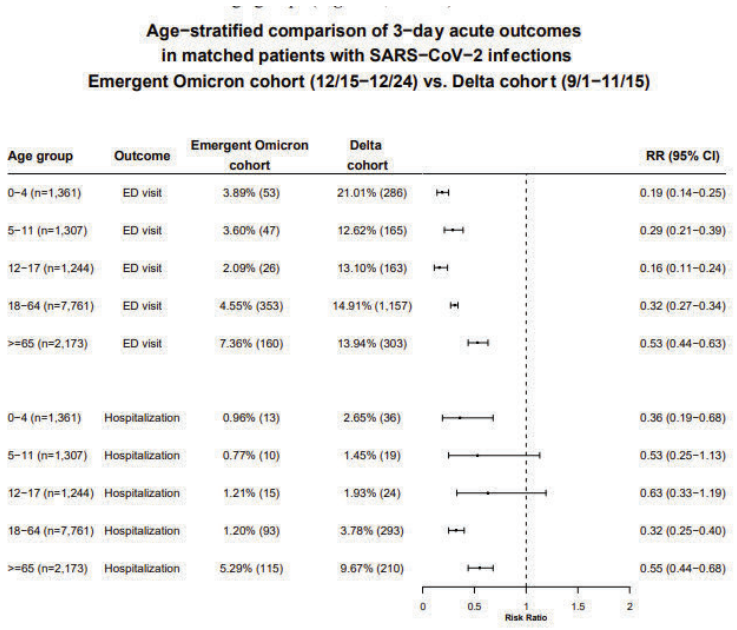
[40] Shabir A. Madhi, Gaurav Kwatra, Jonathan E. Myers, Waasila Jassat, Nisha Dhar, Christian K. Mukendi, Amit J. Nana, Lucille Blumberg, Richard Welch, Nicoletta Ngorima-Mabhena, Portia C. Mutevedzi (2021) *South African Population Immunity and Severe Covid-19 with Omicron Variant*. medRxiv 2021.12.20.21268096; doi: https://doi.org/10.1101/2021.12.20.21268096

[41] https://sacoronavirus.co.za/2021/12/30/media-release-cabinet-approves-changes-to-covid-19-regulations/

> been lower rates of hospitalisation than in previous waves. This means that the country has a spare capacity for admission of patients even for routine health services."

44. In other words, the first country to experience an Omicron wave unambiguously concluded that the dominant variant presents no grave danger.

45. Early U.S. data was available in a preprint from a team at Case Western Reserve University, which used propensity matched-cohort analysis to find markedly reduced disease severity during the period from December 14 to December 24, 2021. On an age and risk-matched basis, they found E.R. visits were 70% lower than earlier cohorts, hospitalizations were 56% lower, ICU admissions were 67% lower, and ventilation were 84% lower.



46. As good as they appear, these reductions substantially *understate* the reduction of risk represented by Omicron, because this cohort included a non-negligible number of Delta infections. According to the authors:

> "The estimated prevalence of the Omicron variant during 12/15-12/24 was only 22.5-58.6%, suggesting that the outcomes for the Omicron variant may be found to be even milder than what we report here as the prevalence of the Omicron variant increases."

47. Quite simply, the Omicron variant is now a *normal respiratory virus,* not an unusual, extraordinary, or grave danger. There is no evidence specific to Omicron to support a grave danger finding.

IV. VACCINES ARE INEFFECTIVE AT PREVENTING OMICRON INFECTIONS

48. Pfizer and BioNTech are the manufacturers of the current leading vaccine. They recently admitted that the existing vaccine does not provide robust protection against Omicron, saying:

> "Sera from individuals who received two doses of the current COVID-19 vaccine did exhibit, on average, more than a 25-fold reduction in neutralization titers against the Omicron variant compared to wild-type, indicating that two doses of BNT162b2 may not be sufficient to protect against infection with the Omicron variant."[42]

49. Moderna, the second-leading manufacturer, similarly admitted that its vaccine does not provide acceptable efficacy against Omicron, stating:

> "All groups had low neutralizing antibody levels in the Omicron PsVNT assay prior to boosting."[43]

50. Similarly, NIH-funded researchers at Duke university found in vitro that: "neutralizing titers to Omicron are 49-84 times

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[42] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-omicron-variant

[43] https://investors.modernatx.com/news/news-details/2021/Moderna-Announces-Preliminary-Booster-Data-and-Updates-Strategy-to-Address-Omicron-Variant/default.aspx

lower than neutralization titers to D614G [wild-type SARS-CoV2] after 2 doses of mRNA-1273 [Moderna], which could lead to an increased risk of symptomatic breakthrough infections."[44]

51. Real-world evidence from at least four countries with significant experience with Omicron — Denmark, the United Kingdom, Germany, and Canada, all of which provide more detailed and transparent data than has been made available in the United States — evidences that these vaccines have *substantially zero efficacy* at preventing Omicron transmission, undermining the central rationale for mandating them in the workplace.

52. The Statens Serum Institut in Copenhagen, Denmark analyzed Danish data and found vaccine efficacy turned *negative* after 91 days following the second dose was administered. In other words, vaccinated Danes were *even more likely* than unvaccinated

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[44] https://www.medrxiv.org/content/10.1101/2021.12.15.21267805v1.full-text

Danes to be infected with Omicron after 3 months.[45] This may be due to unvaccinated, COVID-recovered patients having better[46] protection versus Omicron than vaccinated patients who never previously had COVID.

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45 https://www.medrxiv.org/content/10.1101/2021.12.20.21267966v2.full.pdf

46 Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon (2021) *Comparing SARS-CoV-2 recovered immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, medRxiv 2021.08.24.21262415; doi: https://doi.org/10.1101/2021.08.24.21262415

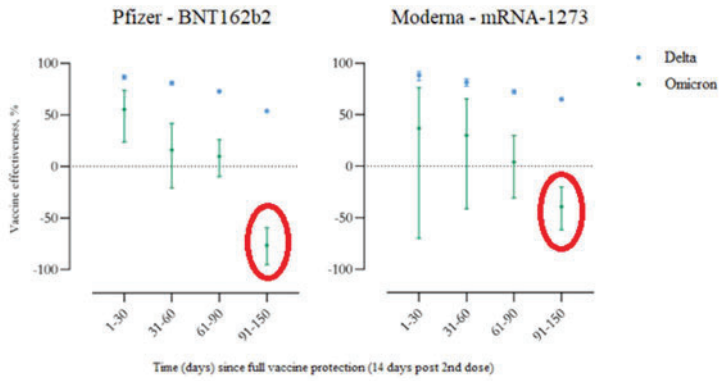

Figure Vaccine effectiveness against SARS-CoV-2 infection with the Delta and Omicron variants, shown separately for the BNT162b2 and mRNA-1273 vaccines. Vertical bars indicate 95% confidence intervals.

Table Estimated vaccine effectiveness for BNT162b2 and mRNA-1273 against infection with the SARS-CoV-2 Omicron and Delta variants during November 20 – December 12, 2021, Denmark.

	Pfizer – BNT162b2				Moderna - mRNA-1273			
Time since vaccine protection	Omicron		Delta		Omicron		Delta	
	Cases	VE, % (95% CI)	Cases	VE, % (95% CI)	Cases	VE, % (95% CI)	Cases	VE, % (95% CI)
1-30 days	14	55.2 (23.5; 73.7)	171	86.7 (84.6; 88.6)	4	36.7 (-69.9; 76.4)	29	88.2 (83.1; 91.8)
31-60 days	32	16.1 (-20.8; 41.7)	454	80.9 (79.0; 82.6)	8	30.0 (-41.3; 65.4)	116	81.5 (77.7; 84.6)
61-90 days	145	9.8 (-10.0; 26.1)	3,177	72.8 (71.7; 73.8)	48	4.2 (-30.8; 29.8)	1,037	72.2 (70.4; 74.0)
91-150 days	2,851	-76.5 (-95.3;-59.5)	34, 947	53.8 (52.9; 54.6)	393	-39.3 (-61.6;-20.0)	3459	65.0 (63.6; 66.3)
1-30 days after booster vaccination protection	29	54.6 (30.4; 70.4)	453	81.2 (79.2; 82.9)	-	-	5	82.8 (58.8; 92.9)

CI = confidence intervals; VE = vaccine effectiveness. VE estimates adjusted for 10-year age groups, sex and region (five geographical regions). Vaccine protection was assumed 14 days post 2nd dose. Insufficient data to estimate mRNA-1273 booster VE against Omicron.

53. In Germany, the most recent detailed report from the Robert Koch Institute (the German equivalent of the CDC) found that 78.6 percent (4,020 of 5,117) of sequenced Omicron cases were in *vaccinated* Germans,[47] despite a population vaccination rate of just 70 percent.[48]

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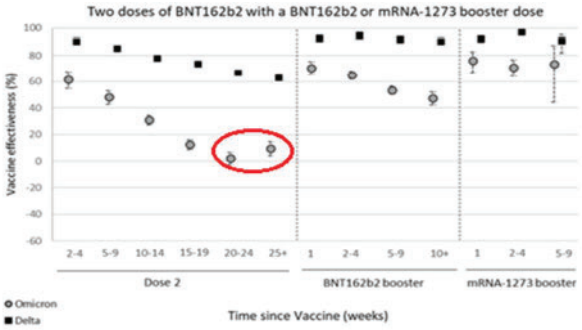
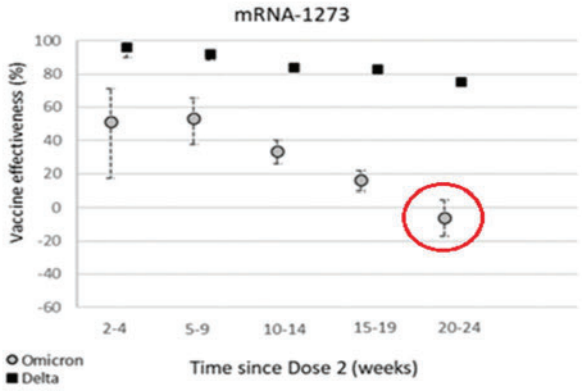
47 https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/Wochenbericht/Wochenbericht_2021-12-30.pdf?__blob=publicationFile

48 https://ourworldindata.org/covid-vaccinations

54. In the United Kingdom, the U.K. Health Security Agency calculated preliminary vaccine effectiveness estimates remarkably like the Danish findings, with *near-zero vaccine efficacy* for both Pfizer-BioNTech and Moderna vaccines after 20 weeks following the second dose:[49]

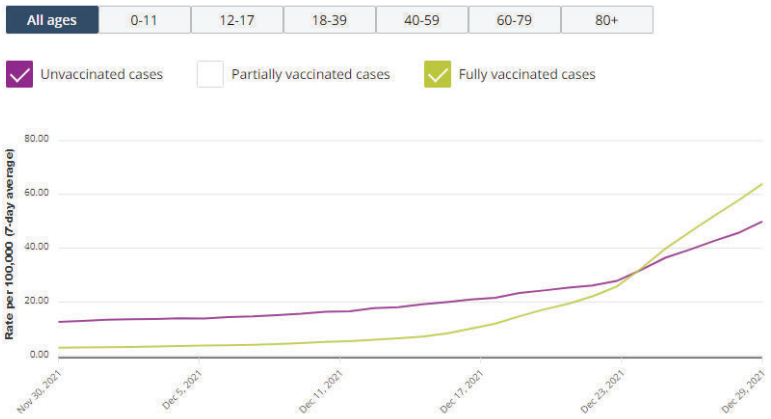




49 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1043807/technical-briefing-33.pdf

55. Although the U.K. Health Security Agency clarifies "[t]hese results should be interpreted with caution due to the low counts and the possible biases related to the populations with highest exposure to Omicron (including travelers and their close contacts) which cannot fully be accounted for," these results are consistent with the epidemiological patterns we are seeing in the United States and globally.

56. In Ontario, Canada, the case rate per 100,000 fully *vaccinated* Ontarians has risen sharply above the case rate per 100,000 unvaccinated Ontarians, again suggesting *negative vaccine efficacy*:[50]



[50] https://covid-19.ontario.ca/data/case-numbers-and-spread

57. A test-negative control analysis of Ontario test data by researchers from Public Health Ontario and leading Canadian universities found: "observed *negative* VE against Omicron among those who had received 2 doses compared to unvaccinated individuals" (emphasis added).

58. As the following table shows, the Ontario researchers found that after day 60 following the second dose, vaccine effectiveness was *negative*, meaning a vaccinated person was *more likely* to be infected than an unvaccinated person:

Table 2. Vaccine effectiveness against infection by Omicron or Delta among adults aged ≥18 years by time since latest dose

Doses	Vaccine products	Days since latest dose	SARS-CoV-2 negative controls, n	Omicron-positive cases, n	Vaccine effectiveness against Omicron (95% CI)	Delta-positive cases, n	Vaccine effectiveness against Delta (95% CI)
First 2 doses	≥1 mRNA vaccine	7-59	14,288	63	6 (-25, 30)	204	84 (81, 86)
		60-119	34,741	214	-13 (-38, 8)	562	81 (79, 82)
		120-179	282,977	2,257	-38 (-61, -18)	4,342	80 (79, 81)
		180-239	47,282	522	-42 (-69, -19)	635	74 (72, 76)
		≥240	10,285	46	-16 (-62, 17)	203	71 (66, 75)
Third dose	Any mRNA vaccine	0-6	10,208	50	2 (-35, 29)	71	88 (85, 90)
		≥7	36,500	114	37 (19, 50)	138	93 (92, 94)
	BNT162b2	0-6	8,461	42	2 (-39, 30)	64	87 (83, 90)
		≥7	30,269	106	34 (16, 49)	116	93 (91, 94)
	mRNA-1273	0-6	1,747	8	5 (-94, 54)	7	93 (86, 97)
		≥7	6,231	8	59 (16, 80)	22	93 (90, 96)

59. In the United States, studies and data from last summer showing higher viral transmission in less vaccinated southern states is now completely obsolete. As the following CDC table demonstrates, in the Omicron wave there is no observable reduction in case rates based on vaccination rates:[51]

[51] https://data.cdc.gov/Case-Surveillance/United-States-COVID-19-Cases-and-Deaths-by-State-o/9mfq-cb36

Difference in Cases in the Month of December: Most Vaccinated States Compared to Least Vaccinated

State	Cases in December 2021	2020	Difference	Fully Vaccinated
Vermont	11,120	2,932	279%	77.4%
Rhode Island	34,434	32,625	6%	76.5%
Maine	25,029	12,225	105%	75.8%
Connecticut	80,792	68,413	18%	74.6%
Massachusetts	176,728	149,046	19%	74.6%
New York	645,476	332,116	94%	71.8%
New Jersey	242,649	160,001	52%	70.5%
Maryland	113,299	79,084	43%	70.4%
Virginia	129,377	114,703	13%	68.0%
Washington	67,731	76,819	-12%	67.9%
Dist. Columbia	25,133	7,431	238%	67.6%
New Hampshire	35,412	23,034	54%	67.2%
Oregon	27,234	38,478	-29%	66.5%
New Mexico	33,567	45,769	-27%	66.2%
Colorado	80,691	100,744	-20%	66.2%
California	308,923	1,018,584	-70%	66.1%
Minnesota	103,065	96,539	7%	65.4%
MOST VACCINATED STATES			45%	70.2%

State	Cases in December 2021	2020	Difference	Fully Vaccinated
Ohio	281,594	279,317	1%	55.2%
West Virginia	30,720	37,492	-18%	55.1%
Kentucky	66,912	88,994	-25%	54.2%
Montana	6,049	19,357	-69%	54.0%
Oklahoma	37,452	105,592	-65%	53.5%
South Carolina	47,894	97,200	-51%	53.1%
Missouri	88,356	111,450	-21%	53.0%
North Dakota	10,403	13,115	-21%	52.6%
Indiana	133,734	172,712	-23%	52.0%
Tennessee	82,063	211,266	-61%	51.4%
Arkansas	28,713	67,779	-58%	51.2%
Georgia	127,565	194,889	-35%	51.1%
Louisiana	45,334	82,861	-45%	50.3%
Mississippi	24,681	63,076	-61%	48.1%
Alabama	43,257	111,713	-61%	47.6%
Wyoming	4,153	11,104	-63%	47.5%
Idaho	11,613	39,379	-71%	46.2%
LEAST VACCINATED STATES			-44%	51.5%

60. The published evidence in the Omicron era comparing vaccine-mediated immunity and recovered immunity continues to find that recovered immunity provides good protection versus severe disease on subsequent infection.[52] A pre-print by the same team of Qatari researchers concludes that COVID recovered patients are very unlikely to cause severe disease or death at least 15 months after initial infection in data spanning the Omicron era.

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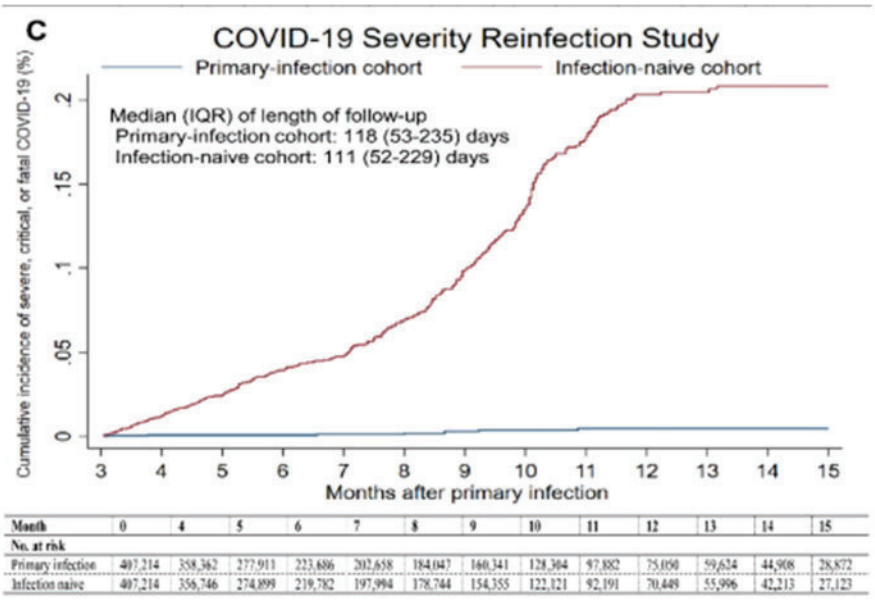
https://covid.cdc.gov/covid-data-tracker/COVIDData/getAjaxData?id=vaccination_data

[52] Altarawneh HN, Chemaitelly H, Ayoub HH, Tang P, Hasan MR, Yassine HM, Al-Khatib HA, Smatti MK, Coyle P, Al-Kanaani Z, Al-Kuwari E, Jeremijenko A, Kaleeckal AH, Latif AN, Shaik RM, Abdul-Rahim HF, Nasrallah GK, Al-Kuwari MG, Butt AA, Al-Romaihi HE, Al-Thani MH, Al-Khal A, Bertollini R, Abu-Raddad LJ. Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections. N Engl J Med. 2022 Jul 7;387(1):21-34. doi: 10.1056/NEJMoa2203965. Epub 2022 Jun 15. PMID: 35704396; PMCID: PMC9258753.

The graph below, reproduced from that paper compares the cumulative incidence of severe reinfection in the study of people who had never had COVID versus those with recovered immunity. At 15 months, the likelihood of severe reinfection for the COVID-recovered group was near zero, while those in the "infection-naïve" cohort was 0.2% of the population.[53]



[53] Chemaitelly H et al. (2022) Duration of immune protection of SARS-CoV-2 natural infection
against reinfection in Qatar. *medRxiv*. July 7, 2022. https://www.medrxiv.org/content/10.1101/2022.07.06.22277306v1.full.pdf

V. Conclusion

61. Based on the scientific evidence to date, for most of the population, COVID-19 infection poses less of a mortality risk than seasonal influenza.

62. Based on the scientific evidence to date, vaccines effectively protect against infection (and therefore disease spread) for only a short period of time.

63. Based on the scientific evidence to date, those who have recovered from a SARS-CoV-2 infection possess immunity as robust and durable (or more) as that acquired through vaccination. The existing clinical literature overwhelmingly indicates that the protection afforded to the individual and community from recovered immunity is as effective and durable as the efficacy levels of the most effective vaccines to date.

64. Based on my analysis of the existing medical and scientific literature, any policy regarding vaccination that does not

recognize recovered immunity is irrational, arbitrary, and counterproductive to community health.[54]

65. Indeed, now that every American adult, teenager, and child six months and above has free access to the vaccines, the case for a vaccine mandate is weaker than it once was. Since the successful vaccination campaign already protects the vast majority of the vulnerable population, the unvaccinated—especially recovered COVID patients—pose a vanishingly small threat to the vaccinated on the margin since such a large portion of that population has already had and recovered from COVID infection. They are protected by an effective vaccine that dramatically reduces the likelihood of hospitalization or death after infections to near zero. At the same time, recovered immunity provides benefits that are at least as strong and may well be stronger than those from vaccines.

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[54] Bhattacharya, J., Gupta, S. & Kulldorff, M. (2021, June 4). *The beauty of vaccines and recovered immunity*. Smerconish Newsletter. https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity

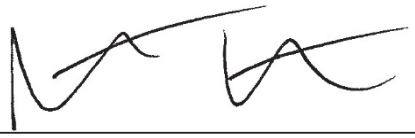
66. Since a large fraction of the unvaccinated population of health care staff are COVID recovered and hence pose little to no more risk of transmission of the virus than vaccinated workers, mandatory healthcare staff vaccination, or proof of immunity, does not have an appreciable effect on COVID-19 transmission within the healthcare setting.

67. Substantial new factual developments related to the Omicron variant substantially undermines any possible justification for the vaccine mandates. Even if SARS-CoV-2 did present a grave danger justifying the mandates at the time they were announced — a highly controversial assertion in its own right — at this time, the Omicron virus that presently dominates the field does not even arguably present a grave danger. Nor could its transmission be substantially reduced through mandatory vaccination even if it did present a grave danger.

68. I declare under penalty of perjury under the laws of the United States of America that, to the best of my knowledge, the foregoing is true and correct.

Executed this 15th day of July, 2022, at Stanford, California.

Respectfully submitted,



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RESEARCH INTERESTS

Health economics, health policy, and outcomes research

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Stanford University	A.M., A.B.	1990
Stanford University School of Medicine	M.D.	1997
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B. EMPLOYMENT HISTORY:

2001 – present	Professor (Assistant to Full), Stanford University School of Medicine, Department of Economics (by courtesy)
2013 – present	Senior Fellow, Stanford Institute for Economic Policy Research
2007 – present	Research Associate, Sphere Institute / Acumen LLC
2002 – present	FRF to Research Associate, National Bureau of Economic Research
2021 – present	Senior Fellow (by courtesy), Hoover Institute, Stanford University
2006 – 2008	Research Fellow, Hoover Institution, Stanford University
2014 – 2021	Senior Fellow (by courtesy) Stanford Freeman Spogli Institute
2001 – 2020	Professor (Assistant to Full) Department of Health Research and Policy (by courtesy)
1998 – 2001	Economist (Associate to Full), RAND Corporation
1998 – 2001	Visiting Assistant Professor, UCLA Department of Economics

C. SCHOLARLY PUBLICATIONS:

PEER-REVIEWED ARTICLES (161 total)

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2. Nguyen C, Hernandez-Boussard T., Davies S, **Bhattacharya J**, Khosla R, Curtin C. *Cleft Palate Surgery: Variables of Quality and Patient Safety*. Presented at the 69th Annual American Cleft-Palate Craniofacial Association (2012). [abstract]
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D. PUBLIC AND PROFESSIONAL SERVICE:

JOURNAL EDITING
Journal of Human Capital, Associate Editor (2015-present)
American Journal of Managed Care, Guest Editor (2016)
Journal of Human Resources, Associate Editor (2011-13)
Forum for Health Economics & Policy, Editorial Board Member (2001-2012)
Economics Bulletin, Associate Editor (2004-2009)

SERVICE ON SCIENTIFIC REVIEW AND ADVISORY COMMITTEES (Selected)

- Standing member of the Health Services Organization and Delivery (HSOD) NIH review panel, 2012-2016
- NIH reviewer (various panels, too numerous to list) 2003-present
- NIH Review Panel Chair: 2018 (P01 review), 2020 (DP1 review).
- Invited Reviewer for the European Research Council, ERC Advanced Grant 2015 RFP
- NIH Stage 2 Challenge Grant Review Panel, July 2009
- Appointed a member of an Institute of Medicine (IOM) panel on the regulation of work hours by resident physicians, 2007-8.
- Standing member of the NIH Social Science and Population Studies Review Panel, Fall 2004-Fall 2008
- Invited Reviewer for National Academy of Sciences report on Food Insecurity and Hunger, November 2005.

- Invited Reviewer for the National Academy of Sciences report on the Nutrition Data Infrastructure, December 2004
- Invited Reviewer for the National Institute on Health (NIH) Health Services Organization and Delivery Review Panel, June 2004, Alexandria, VA.
- Invited Reviewer for the Food Assistance and Nutrition Research Program US Department of Agriculture Economic Research Service Research Proposal Review Panel, June 2004, Stanford, CA.
- Invited Reviewer for the National Institute on Health (NIH) Social Science and Population Studies Review Panel, February 2004, Alexandria, VA.
- Invited Reviewer for the National Institute on Health (NIH) Social Sciences and Population Studies Review Panel, November 2003, Bethesda, MD.
- Invited Reviewer for the National Institute on Health (NIH) Social Science, Nursing, Epidemiology, and Methods (3) Review Panel, June 2003, Bethesda, MD.
- Invited Reviewer for the Food Assistance and Nutrition Research Program US Department of Agriculture Economic Research Service Research Proposal Review Panel, August 2002.
- Research Advisory Panel on Canadian Disability Measurement, Canadian Human Resources Development Applied Research Branch, June 2001 in Ottowa, Canada.
- Invited Reviewer for the National Institute of Occupational Safety and Health R18 Demonstration Project Grants Review panel in July 2000, Washington D.C.
- Research Advisory Panel on Japanese Health Policy Research. May 1997 at the Center for Global Partnership, New York, NY.

TESTIMONY TO GOVERNMENTAL PANELS AND AGENCIES (9)

- US Senate Dec. 2020 hearing of the Subcommittee on Homeland Security and Governmental Affairs. Testimony provided on COVID-19 mortality risk, collateral harms from lockdown policies, and the incentives of private corporations and the government to invest in research on low-cost treatments for COVID-19 disease
- "Roundtable on Safe Reopening of Florida" led by Florida Gov. Ron DeSantis. September 2020.
- "Evaluation of the Safety and Efficacy of COVID-19 Vaccine Candidates" July 2020 hearing of the House Oversight Briefing to the Economic and Consumer Policy Subcommittee.
- US Senate May 2020 virtual roundtable. Safely Restarting Youth Baseball and Softball Leagues, invited testimony
- "Population Aging and Financing Long Term Care in Japan" March 2013 seminar at the Japanese Ministry of Health.
- "Implementing the ACA in California" March 2011 testimony to California Legislature Select Committee on Health Care Costs.
- "Designing an Optimal Data Infrastructure for Nutrition Research" June 2004 testimony to the National Academy of Sciences commission on "Enhancing the Data Infrastructure in Support of Food and Nutrition Programs, Research, and Decision Making," Washington D.C.

- "Measuring the Effect of Overtime Reform" October 1998 testimony to the California Assembly Select Committee on the Middle Class, Los Angeles, CA.
- "Switching to Weekly Overtime in California." April 1997 testimony to the California Industrial Welfare Commission, Los Angeles, CA.

REFEREE FOR RESEARCH JOURNALS

American Economic Review; American Journal of Health Promotion; American Journal of Managed Care; Education Next; Health Economics Letters; Health Services Research; Health Services and Outcomes Research Methodology; Industrial and Labor Relations Review; Journal of Agricultural Economics; Journal of the American Medical Association; Journal of Health Economics; Journal of Health Policy, Politics, and Law; Journal of Human Resources; Journal of Political Economy; Labour Economics; Medical Care; Medical Decision Making; Review of Economics and Statistics; Scandinavian Journal of Economics; Social Science and Medicine; Forum for Health Economics and Policy; Pediatrics; British Medical Journal

Trainee	**Current Position**
Peter Groeneveld, MD, MS	Associate Professor of Medicine, University of Pennsylvania
Jessica Haberer, MD, MS	Assistant Professor of Medicine, Harvard Medical School
Melinda Henne, MD, MS	Director of Health Services Research, Bethesda Naval Hospital
Byung-Kwang Yoo, MD, PhD	Associate Professor, Public Health, UC Davis
Hau Liu, MD, MS, MBA	Chief Medical Officer at Shanghai United Family Hospital
Eran Bendavid, MD, MS	Assistant Professor, General Medicine Disciplines, Stanford University
Kaleb Michaud, MS, PhD	Associate Professor of Medicine, Rheumatology and Immunology, University of Nebraska Medical Center
Kanaka Shetty, MD	Natural Scientist, RAND Corporation
Christine Pal Chee, PhD	Associate Director of the Health Economics Resource Center, Palo Alto VA
Matthew Miller, MD	VP Clinical Strategy and Head of Innovation, Landmark Health
Vincent Liu, MD	Research Scientist, Kaiser Permanente Northern California Division of Research
Daniella Perlroth, MD	Chief Data Scientist, Lyra Health
Crystal Smith-Spangler, MD	Internist, Palo Alto Medical Foundation
Barrett Levesque, MD MS	Assistant Professor of Clinical Medicine, UC San Diego Health System
Torrey Simons, MD	Clinical Instructor, Department of Medicine, Stanford University
Nayer Khazeni, MD	Assistant Professor of Medicine (Pulmonary and Critical Care Medicine), Stanford University
Monica Bhargava, MD MS	Assistant Clinical Professor, UCSF School of Medicineilan
Dhruv Kazi, MD	Assistant Professor, UCSF School of Medicine
Zach Kastenberg, MD	Resident, Department of Surgery, Stanford University
Kit Delgado, MD	Assistant Professor, Department of Emergency Medicine and Faculty Fellow, University of Pennsylvania
Suzann Pershing, MD	Chief of Ophtalmology for the VA Palo Alto Health Care System
KT Park, MD	Assistant Professor, Department of Medicine, Stanford University
Jeremy Goldhaber-Fiebert, PhD	Associate Professor, Department of Medicine, Stanford University
Sanjay Basu, MD	Assistant Professor, Department of Medicine, Stanford University
Marcella Alsan, MD, PhD	Assistant Professor, Department of Medicine (CHP/PCOR), Stanford Univ.
David Chan, MD, PhD	Assistant Professor, Department of Medicine (CHP/PCOR), Stanford Univ.
Karen Eggleston, PhD	Senior Fellow, Freeman Spogli Institute, Stanford University
Kevin Erickson, MD	Assistant Professor, Department of Nephrology, Baylor College of Medicine
Ilana Richman, MD	VA Fellow at CHP/PCOR, Stanford University
Alexander Sandhu, MD	VA Fellow at CHP/PCOR, Stanford University

Michael Hurley	Medical Student, Stanford University
Manali Patel, MD	Instructor, Department of Medicine (Oncology), Stanford University
Dan Austin, MD	Resident Physician, Department of Anesthesia, UCSF School of Medicine
Anna Luan, MD	Resident Physician, Department of Medicine, Stanford University
Louse Wang	Medical Student, Stanford University
Christine Nguyen, MD	Resident Physician, Department of Medicine, Harvard Medical School
Josh Mooney, MD	Instructor, Department of Medicine (Pulmonary and Critical Care Medicine), Stanford University
Eugene Lin, MD	Fellow, Department of Medicine (Nephrology), Stanford University
Eric Sun, MD	Assistant Professor, Department of Anesthesia, Stanford University
Sejal Hathi	Medical Student, Stanford University
Ibrahim Hakim	Medical Student, Stanford University
Archana Nair	Medical Student, Stanford University
Trishna Narula	Medical Student, Stanford University
Daniel Vail	Medical Student, Stanford University
Tej Azad	Medical Student, Stanford University
Jessica Yu, MD	Fellow, Department of Medicine (Gastroenterology), Stanford University
Daniel Vail	Medical Student, Stanford University
Alex Sandhu, MD	Fellow, Department of Medicine (Cardiology), Stanford University
Matthew Muffly, MD	Clinical Assistant Professor, Dept. of Anesthesia, Stanford University

Dissertation Committee Memberships

Ron Borzekowski	Ph.D. in Economics	Stanford University	2002
Jason Brown	Ph.D. in Economics	Stanford University	2002
Dana Rapaport	Ph.D. in Economics	Stanford University	2003
Ed Johnson	Ph.D. in Economics	Stanford University	2003
Joanna Campbell	Ph.D. in Economics	Stanford University	2003
Neeraj Sood*	Ph.D. in Public Policy	RAND Graduate School	2003
James Pearce	Ph.D. in Economics	Stanford University	2004
Mikko Packalen	Ph.D. in Economics	Stanford University	2005
Kaleb Michaud*	Ph.D. in Physics	Stanford University	2006
Kyna Fong	Ph.D. in Economics	Stanford University	2007
Natalie Chun	Ph.D. in Economics	Stanford University	2008
Sriniketh Nagavarapu	Ph.D in Economics	Stanford University	2008
Sean Young	Ph.D. in Psychology	Stanford University	2008
Andrew Jaciw	Ph.D. in Education	Stanford University	2010
Chirag Patel	Ph.D. in Bioinformatics	Stanford University	2010
Raphael Godefroy	Ph.D. in Economics	Stanford University	2010
Neal Mahoney	Ph.D. in Economics	Stanford University	2011
Alex Wong	Ph.D. in Economics	Stanford University	2012
Kelvin Tan	Ph.D. in Management Science	Stanford University	2012
Animesh Mukherjee	Masters in Liberal Arts Program	Stanford University	2012
Jeanne Hurley	Masters in Liberal Arts Program	Stanford University	2012
Patricia Foo	Ph.D. in Economics	Stanford University	2013
Michael Dworsky	Ph.D. in Economics	Stanford University	2013
Allison Holliday King	Masters in Liberal Arts Program	Stanford University	2013
Vilsa Curto	Ph.D. in Economics	Stanford University	2015
Rita Hamad	Ph.D. in Epidemiology	Stanford University	2016
Atul Gupta	Ph.D. in Economics	Stanford University	2017
Yiwei Chen	Ph.D. in Economics	Stanford University	2019
Yiqun Chen	Ph.D. in Health Policy	Stanford University	2020
Min Kim	Ph.D. in Economics	Iowa State Univ.	2021
Bryan Tysinger	Ph.D. in Public Policy	RAND Graduate School	2021

E. GRANTS AND PATENTS

PATENT (2)

1. "Environmental Biomarkers for the Diagnosis and Prognosis for Type 2 Diabetes Mellitus" with Atul Butte and Chirag Patel (2011), US Patent (pending).
2. "Health Cost and Flexible Spending Account Calculator" with Schoenbaum M, Spranca M, and Sood N (2008), U.S. Patent No. 7,426,474.

GRANTS AND SUBCONTRACTS (42)

CURRENT (6)

2019-2020	Funder: Acumen, LLC. Title: Quality Reporting Program Support for the Long-Term Care Hospital, Inpatient Rehabilitation Facility, Skilled Nursing Facility QRPs and Nursing Home Compare Role: PI
2018-2020	Funder: Acumen, LLC. Title: Surveillance Activities of Biologics Role: PI
2018-2020	Funder: France-Stanford Center for Interdisciplinary Studies Title: A Nutritional Account of Global Trade: Determinants and Health Implications Role: PI
2017-2023	Funder: National Institutes of Health Title: The Epidemiology and Economics of Chronic Back Pain Role: Investigator (PI: Sun)
2017-2021	Funder: National Institutes of Health Title: Big Data Analysis of HIV Risk and Epidemiology in Sub-Saharan Africa Role: Investigator (PI: Bendavid)
2016-2020	Funder: Acumen, LLC. Title: MACRA Episode Groups and Resource Use Measures II Role: PI

PREVIOUS (36)

2016-2018	Funder: University of Kentucky Title: Food acquisition and health outcomes among new SNAP recipients since the Great Recession Role: PI

2015-2019	Funder: Alfred P. Sloan Foundation Title: Public versus Private Provision of Health Insurance Role: PI
2015-2019	Funder: Natural Science Foundation Title: Health Insurance Competition and Healthcare Costs Role: Investigator (PI: Levin)
2014-2015	Funder: The Centers for Medicare and Medicaid Services Title: Effect of Social Isolation and Loneliness on Healthcare Utilization Role: PI
2014-2015	Funder: AARP Title: The Effect of Social Isolation and Loneliness on Healthcare Utilization and Spending among Medicare Beneficiaries Role: PI
2013-2019	Funder: National Bureau of Economic Research Title: Innovations in an Aging Society Role: PI
2013-2014	Funder: Robert Wood Johnson Foundation Title: Improving Health eating among Children through Changes in Supplemental Nutrition Assistance Program (SNAP) Role: Investigator (PI: Basu)
2011-2016	Funder: National Institutes of Health (R37) Title: Estimating the Potential Medicare Savings from Comparative Effectiveness Research Role: PI Subaward (PI: Garber)
2011-2016	Funder: National Institute of Aging (P01) Title: Improving Health and Health Care for Minority and Aging Populations Role: PI Subcontract (PI: Wise)

2010-2018	Funder: National Institutes of Health Title: Clinic, Family & Community Collaboration to Treat Overweight and Obese Children Role: Investigator (PI: Robinson)
2010-2014	Funder: Agency for Health, Research and Quality (R01) Title: The Effects of Private Health Insurance in Publicly Funded Programs Role: Investigator (PI: Bundorf)
2010-2013	Funder: Agency for Healthcare Research and Quality Title: G-code" Reimbursement and Outcomes in Hemodialysis Role: Investigator (PI: Erickson)
2010-2013	Funder: University of Southern California Title: The California Medicare Research and Policy Center Role: PI
2010-2012	Funder: University of Georgia Title: Natural Experiments and RCT Generalizability: The Woman's Health Initiative Role: PI
2010-2011	Funder: National Bureau of Economic Research Title: Racial Disparities in Health Care and Health Among the Elderly Role: PI
2009-2020	Funder: National Institute of Aging (P30) Title: Center on the Demography and Economics of Health and Aging Role: PI (2011-2020)
2009-2011	Funder: Rand Corporation Title: Natural Experiments and RCT Generalizability: The Woman's Health Initiative Role: PI
2008-2013	Funder: American Heart Association Title: AHA-PRT Outcomes Research Center Role: Investigator (PI: Hlatky)
2007-2009	Funder: National Institute of Aging (R01) Title: The Economics of Obesity Role: PI
2007-2009	Funder: Veterans Administration, Health Services Research and Development Service Title: Quality of Practices for Lung Cancer Diagnosis and Staging Role: Investigator
2007-2008	Funder: Stanford Center for Demography and Economics of Health and Aging

	Title: The HIV Epidemic in Africa and the Orphaned Elderly Role: PI
2007	Funder: University of Southern California Title: The Changes in Health Care Financing and Organization Initiative Role: PI
2006-2010	Funder: National Institute of Aging (K02) Title: Health Insurance Provision for Vulnerable Populations Role: PI
2006-2010	Funder: Columbia University/Yale University Title: Dummy Endogenous Variables in Threshold Crossing Models, with Applications to Health Economics Role: PI
2006-2007	Funder: Stanford Center for Demography and Economics of Health and Aging Title: Obesity, Wages, and Health Insurance Role: PI
2005-2009	Funder: National Institute of Aging (P01 Subproject) Title: Medical Care for the Disabled Elderly Role: Investigator (PI: Garber)
2005-2008	Funder: National Institute of Aging (R01) Title: Whom Does Medicare Benefit? Role: PI Subcontract (PI: Lakdawalla)
2002	Funder: Stanford Center for Demography and Economics of Health and Aging Title: Explaining Changes in Disability Prevalence Among Younger and Older American Populations Role: PI
2001-2003	Funder: Agency for Healthcare Research and Quality (R01) Title: State and Federal Policy and Outcomes for HIV+ Adults Role: PI Subcontract (PI: Goldman)
2001-2002	Funder: National Institute of Aging (R03) Title: The Economics of Viatical Settlements Role: PI
2001-2002	Funder: Robert Woods Johnson Foundation Title: The Effects of Medicare Eligibility on Participation in Social Security Disability Insurance Role: PI Subcontract (PI: Schoenbaum)
2001-2002	Funder: USDA Title: Evaluating the Impact of School Breakfast and Lunch Role: Investigator
2001-2002	Funder: Northwestern/Univ. of Chicago Joint Center on Poverty Title: The Allocation of Nutrition with Poor American Families Role: PI Subcontract (PI: Haider)
2000-2002	Funder: National Institute on Alcohol Abuse & Alcoholism (R03) Title: The Demand for Alcohol Treatment Services Role: PI

2000-2001 Funder: USDA
Title: How Should We Measure Hunger?
Role: PI Subcontract (PI: Haider)

F. SCHOLARSHIPS AND HONORS

- Phi Beta Kappa Honor Society, 1988
- Distinction and Departmental Honors in Economics, Stanford University, 1990
- Michael Forman Fellowship in Economics, Stanford University, 1991-1992
- Agency for Health Care Policy and Research Fellowship 1993-1995
- Outstanding Teaching Assistant Award, Stanford University, Economics, 1994
- Center for Economic Policy Research, Olin Dissertation Fellowship, 1997-1998
- Distinguished Award for Exceptional Contributions to Education in Medicine, Stanford University, 2005, 2007, and 2013.
- Dennis Aigner Award for the best applied paper published in the *Journal of Econometrics*, 2013

G. LIST OF CASES IN WHICH I PREVIOUSLY OFFERED EXPERT WITNESS TESTIMONY

- *R.K., et al. v. Lee*, No. 3:21-cv-00725 (M.D. Tenn. 2021)
- *SID BOYS CORP. d/b/a Kellogg's Diner, and 143 Cafe Inc. d/b/a Toscana v. Cuomo, et al.*, No. 1:20-cv-6249 (E.D.N.Y. 2020)
- *Tandon v. Newsom*, No. 5:20-cv-07108-LHK (N.D.Cal. 2020)
- *Kane v. De Blasio,* No. 21-CV-7863 (VEC), 2021 U.S. Dist. LEXIS 239124 (S.D.N.Y. Dec. 2021)
- *Netzer Law Office, P.C. and Donald L. Netzer v. Montana*, DV-2021-089 (Mont. Seventh Jud. Dist. 2021).
- *UnifySCC v. Cody*, No. 22-cv-01019-BLF, 2022 U.S. Dist. LEXIS 116386 (N.D. Cal. June 30, 2022)
- *Calvary Chapel of Ukiah v. Newsom*, 524 F. Supp. 3d 986, 1000 (E.D. Cal. 2021)
- *Gateway City Church v. Newsom*, 516 F. Supp. 3d 1004, 1020 (N.D. Cal. 2021)
- *Brach v. Newsom*, No. 2:20-cv-06472-SVW-AFM, 2020 U.S. Dist. LEXIS 232008 (C.D. Cal. 2020)
- *S. Bay United Pentecostal Church v. Newsom*, 494 F. Supp. 3d 785 (S.D. Cal. 2020)
- *Hernandez v. Grisham*, 494 F. Supp. 3d 1044 (D.N.M. 2020)
- *DeSantis v. Fla. Educ. Ass'n,* 306 So. 3d 1202 (Fla. Dist. Ct. App. 2020)
- *Cty. of L.A. Dep't of Pub. Health v. Superior Court,* 61 Cal. App. 5th 478, 275 Cal. Rptr. 3d 752 (2021) and *California Restaurant Association, Inc. v. County of Los Angeles Department of Public Health*, No. 20STCP03881 (Cal.Super. 2020)
- *Cross Culture Christian Ctr. v. Newsom*, 445 F. Supp. 3d 758, 763 (E.D. Cal. 2020)

DATED this 15th day of July, 2022.

Austin Knudsen
Montana Attorney General

DAVID M.S. DEWHIRST
Solicitor General

/s/ Brent Mead
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Attorneys for Defendants

CERTIFICATE OF SERVICE

I certify a true and correct copy of the foregoing was delivered by email to the following:

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Date: July 15, 2022

Dia C. Lang

Dia C. Lang

Exhibit 7

AUSTIN KNUDSEN
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Attorneys for Defendants

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MONTANA, MISSOULA DIVISION

MONTANA MEDICAL ASSOCIATION, ET. AL.,

Plaintiffs,

and

MONTANA NURSES ASSOCIATION,

Plaintiff-Intervenors,

v.

AUSTIN KNUDSEN, ET AL.,

DEFENDANTS.

No. CV-21-108-M-DWM

EXPERT REPORT OF RAM DURISETI MD, PHD

Expert Report of Ram Duriseti MD, PhD

July 15th, 2022

I, Ram Duriseti, MD, PhD, declare as follows:

I am a clinical associate professor at the Stanford Emergency Department. I have been a practicing Board Certified Emergency Physician for over 20 years. My PhD background is in computational decision modeling, simulation, and optimization algorithms. I have personal knowledge of the facts set forth below and could testify competently to them if called to do so. A true and correct copy of my *curriculum vitae* is attached to this declaration.

I am being compensated $300.00 per hour for my effort in this case. My compensation is in no way contingent upon my conclusions in this case.

COVID-19 is the disease caused by infection with the SARS-CoV-2 virus. The current generation of COVID-19 vaccines do not significantly limit transmission. Transmission of an infectious disease is both a function of behavior and presence of infection. A vaccine mandate with

the purpose of limiting transmission must not simply decrease the risk of infection, but must do so by a substantial margin.

We must first acknowledge, using the Pfizer COVID-19 mRNA vaccine as a canonical example, that the vaccine trials were never designed to test for preventing transmission. Pfizer themselves pointed this out to the FDA.[1] The "data gaps" identified by Pfizer were:

- Duration of protection
- Effectiveness in certain populations at high risk of severe COVID-19
- Effectiveness in individuals previously infected with SARS-CoV-2
- Future vaccine effectiveness as influenced by characteristics of the pandemic, changes in the virus, and/or potential effects of co-infections
- Vaccine effectiveness against asymptomatic infection
- Vaccine effectiveness against long-term effects of COVID-19 disease

[1] https://www.fda.gov/media/148542/download#page=38

- Vaccine effectiveness against mortality
- Vaccine effectiveness against transmission of SARS-CoV-2

It's important to remember that the original Pfizer trial supporting its FDA approval was never structured to test for transmission reduction and this is part of the record in the Emergency Use Authorization (EUA) review. As noted by Dr. Patrick Moore of the University of Pittsburgh Cancer Institute,

> "One question that addresses these two discussion items, I find is really, really central, and important, is that FDA did not ask in its guidance and Pfizer has presented no evidence in its data today that the vaccine has any effect on virus carriage or shedding, which is the fundamental basis for herd immunity (page 342 of transcription)." [2]

While many COVID-19 immune naïve individuals (no prior infection by SARS-CoV-2 which is the virus that causes COVID-19) likely benefitted from having their immune systems primed by a vaccine prior to a subsequent infection thereby increasing their protection from more severe disease progression, any imputed impact on disease transmission has been fleeting at best.

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[2] https://www.fda.gov/media/144859/download

As early as Summer 2021, emerging data suggested that vaccinated individuals' net reduction in "viral load" during an infection was no more than 30%.[3] Since that time, between waning efficacy and partial "immune escape" from SARS-CoV-2 variants, it's become clear that even that degree of reduction is not sustained. In a more recent study, researchers used longitudinal sampling of nasal swabs for determination of viral load, sequencing, and viral culture in outpatients with newly diagnosed coronavirus disease 2019 (Covid-19). From July 2021 through January 2022 and concluded that, "we did not find large differences in the median duration of viral shedding among participants who were unvaccinated, those who were vaccinated but not boosted, and those who were vaccinated and boosted".[4]

When discussing the topic of transmission in a health care setting and staff vaccination rates, a July 2021 paper examined infection rates among different vaccinated patient cohorts in a nursing home at different levels of staff vaccination. The most telling table was in the supplement.

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[3] https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1.full-text

[4] https://www.nejm.org/doi/full/10.1056/NEJMc2202092

In table S3, there was no association between staff vaccination rates and transmission to residents regardless of the residents' vaccination status.[5] As this study was pre-Delta and pre-Omicron, given increased escape from vaccine induced immunity with both Delta and Omicron variants, there is no reason to believe that this trend would not hold.

NURSING HOME VACCINATIONS 8

Table S3. Incident SARS-CoV-2 infections in residents living in nursing homes with low, moderate, and high staff vaccination rates

	Low staff vaccination (Less than 58.7% of staff vaccinated)		Moderate staff vaccination (58.7 - 69.2% of staff vaccinated)		High staff vaccination (69.3 - 95.7% of staff vaccinated)	
	Total	Percent (%) asymptomatic	Total	Percent (%) asymptomatic	Total	Percent (%) asymptomatic
Residents vaccinated with at least dose 1, n	5691		6291		6260	
Tested positive 0-14 days after dose 1, n(%)	266 (4.7%)	71.1%	267 (4.2%)	74.2%	289 (4.6%)	69.2%
Tested positive 15-28 days after dose 1, n(%)	83 (1.5%)	75.9%	50 (0.8%)	62.0%	117 (1.9%)	72.6%
Residents vaccinated with doses 1 & 2, n	4001		4579		4468	
Tested positive 0-14 days after dose 2, n(%)	46 (1.1%)	80.4%	32 (0.7%)	87.5%	52 (1.2%)	86.5%
Tested positive >14 days after dose 2, n(%)	18 (0.4%)	72.2%	8 (0.2%)	75.0%	12 (0.3%)	83.3%
Unvaccinated residents	1629		1296		1065	
Tested positive 0-14 days after clinic 1 held, n(%)	73 (4.5%)	65.8%	65 (5.0%)	66.2%	35 (3.3%)	68.6%
Tested positive 15-28 days after clinic 1 held, n(%)	31 (1.9%)	64.5%	15 (1.2%)	46.7%	23 (2.2%)	65.2%
Tested positive 29-42 days after clinic 1 held, n(%)	6 (0.4%)	83.3%	4 (0.3%)	75.0%	6 (0.6%)	83.3%
Tested positive >42 days after clinic 1 held, n(%)	6 (0.4%)	83.3%	3 (0.2%)	66.7%	3 (0.3%)	100.0%

Notes. Nursing homes stratified by tertiles of staff vaccination rates as of February 17, 2021. Staff vaccinations occurred simultaneously with resident vaccinations and rates were tracked by the organization.

What about transmission and vaccination/booster status with Omicron? An early December 2021 paper in Danish Households demonstrated a roughly 40% reduction in household secondary attack rate (SAR) with boosting when compared to the unvaccinated or

5 https://www.nejm.org/doi/suppl/10.1056/NEJMc2104849/suppl_file/nejmc2104849_appendix.pdf

vaccinated.[6] Most importantly, there was no such reduction in susceptibility to infection when comparing vaccinated alone compared to the vaccinated. Focusing on table 2, during the early December 2021 study period, booster vaccination cut the risk of contracting Omicron by roughly 45%+ and passing on Omicron by roughly 40%.[5] While this appeared promising for boosters, the subsequent ecological waves from late December 2022 forward in heavily boosted countries previously lauded for the "COVID success" demonstrated otherwise. Denmark, Iceland, Norway, New Zealand, Australia, Hong Kong, South Korea all experienced per-capital COVID waves larger than any experienced by the United States.[7] So the advantage of boosting, while demonstrable in an 8-week time frame, appears to rapidly devolve over time.

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6 https://www.medrxiv.org/content/10.1101/2021.12.27.21268278v1.full.pdf

7 https://ourworldindata.org/explorers/coronavirus-data-explorer?zoomToSelection=true&time=2020-03-01..latest&facet=none&pickerSort=asc&pickerMetric=location&Metric=Confirmed+cases&Interval=7-day+rolling+average&Relative+to+Population=true&Color+by+test+positivity=false&country=USA~ISL~DNK~NOR~KOR~NZL~AU

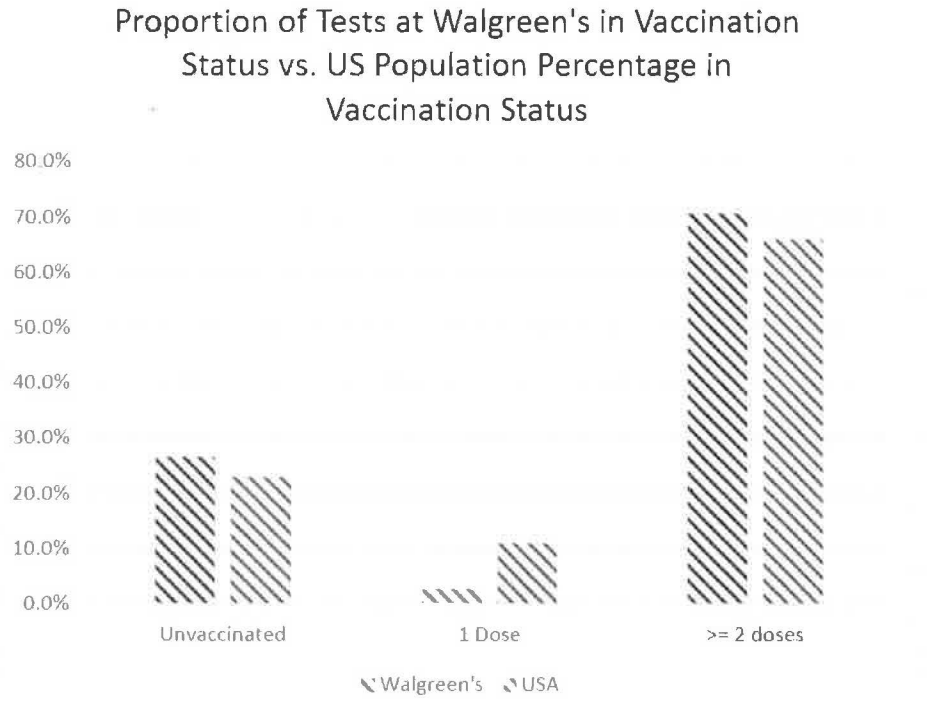
Indeed, we are seeing this effect even more so now across multiple data sets: both national and local.

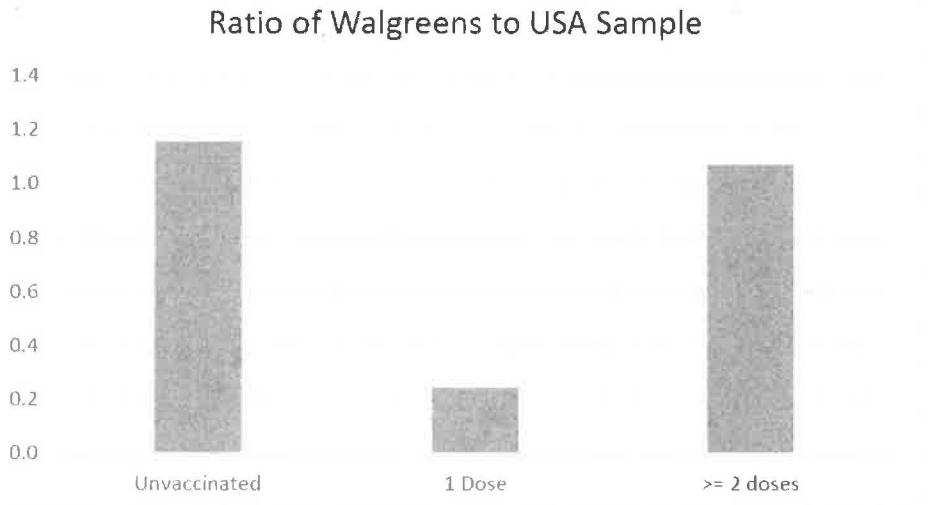
Walgreens is a leading nationwide provider of COVID vaccination and testing provider. They maintain a remarkable COVID dashboard that details test positivity by vaccination status broken down by age cohort.[8] Correcting for vaccination rates and population representation. The data show that vaccinated and boosted individuals are testing positive for COVID-19 at a higher rate than unvaccinated individuals. While there is a chance this reflects the fact that unvaccinated individuals are more likely to have had protection from a prior infection and more likely required to obtain surveillance testing, this does not impact our discussion here as the vast majority of Americans, vaccinated or not, have had a COVID-19 infection (approximately 75% through February 2022 alone).[9]

The Walgreen's data is not excessively sampling vaccinated patients. In fact, the population tested by Walgreens has a small number of single-dose vaccinated than the USA population, with higher

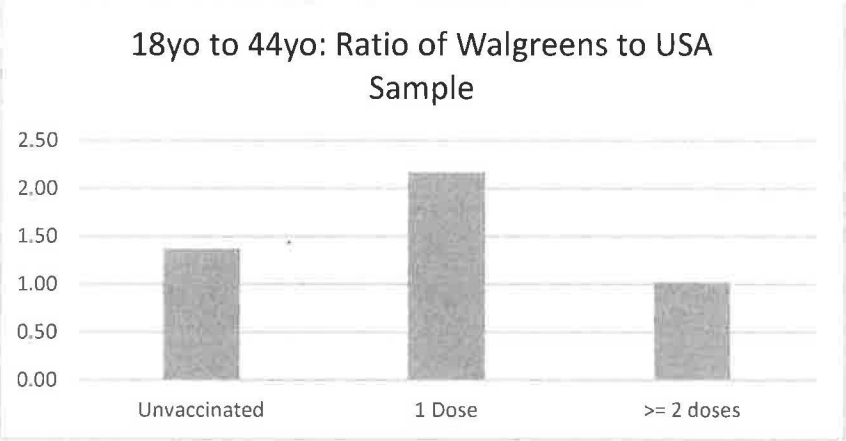
[8] https://www.walgreens.com/businesssolutions/covid-19-index.jsp
[9] https://covid19serohub.nih.gov/

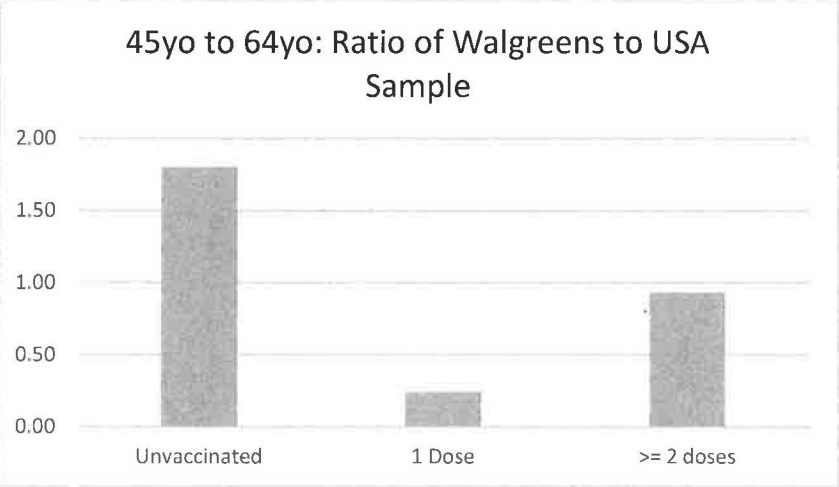
proportions of vaccinated and unvaccinated patients – particularly the unvaccinated.

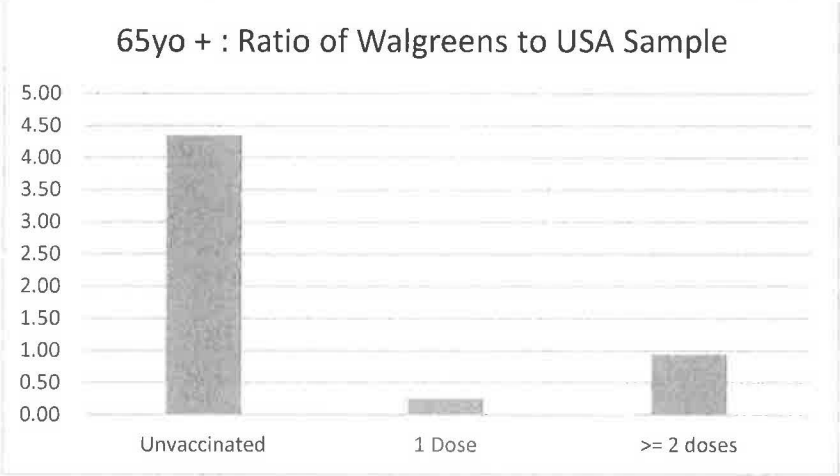




In fact, in the over 18-year-old age cohorts, Walgreen's tests unvaccinated patients at significantly higher rate than their representation in the USA population:

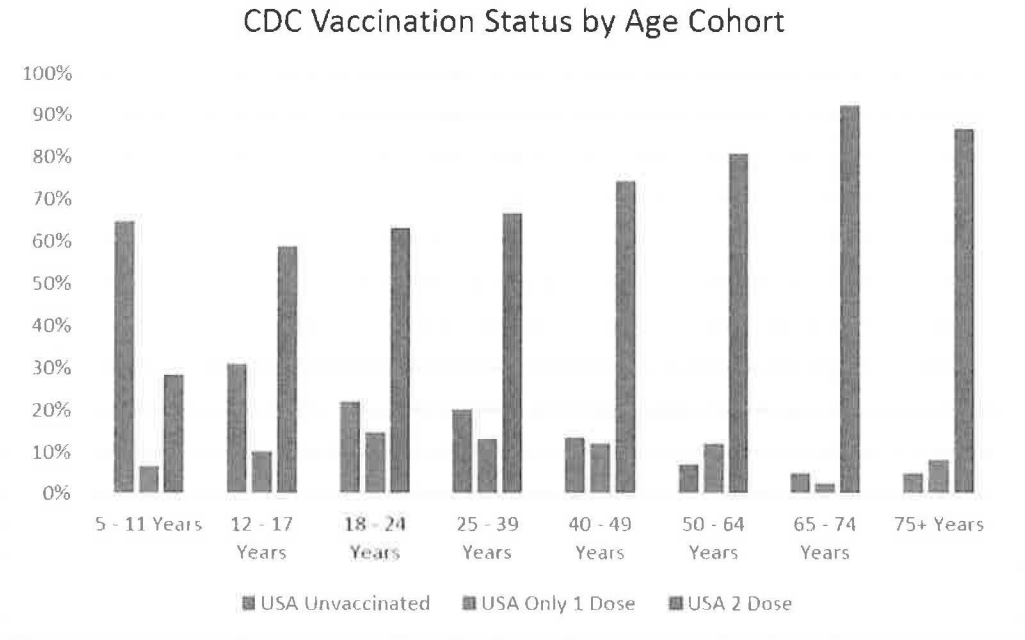




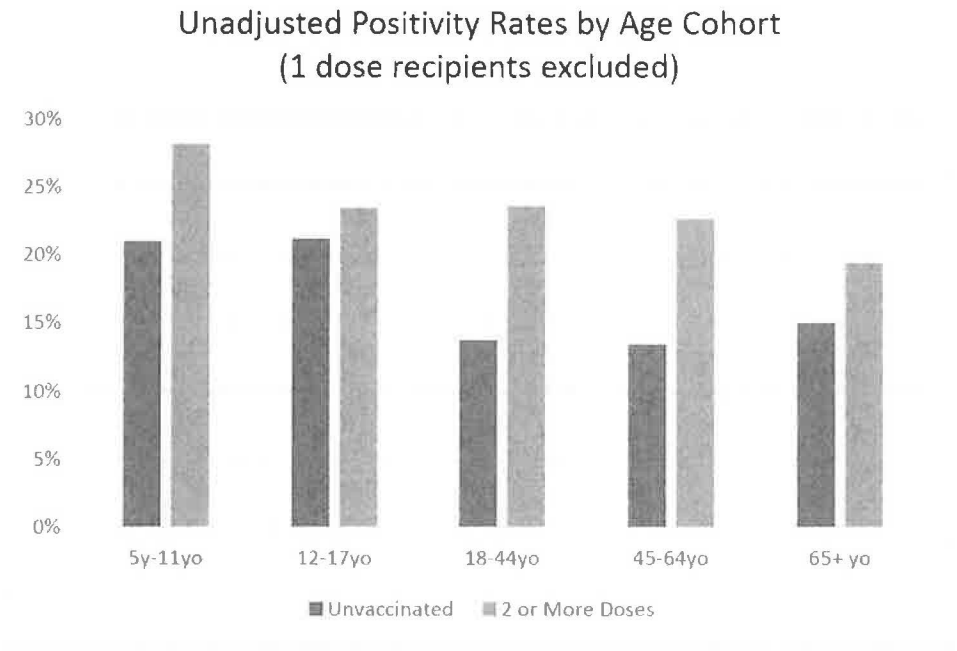


When collecting Walgreens data for a testing week April 28th, 2022, for every age cohort, vaccinated individuals are testing positive at a *higher rate*. It's important to understand that these are rates so there is no "base rate fallacy". In other words, just because vaccinated individuals are a larger percentage of the population, they will not register a higher rate of positivity.

CDC data by dose per age cohort through April 2022:

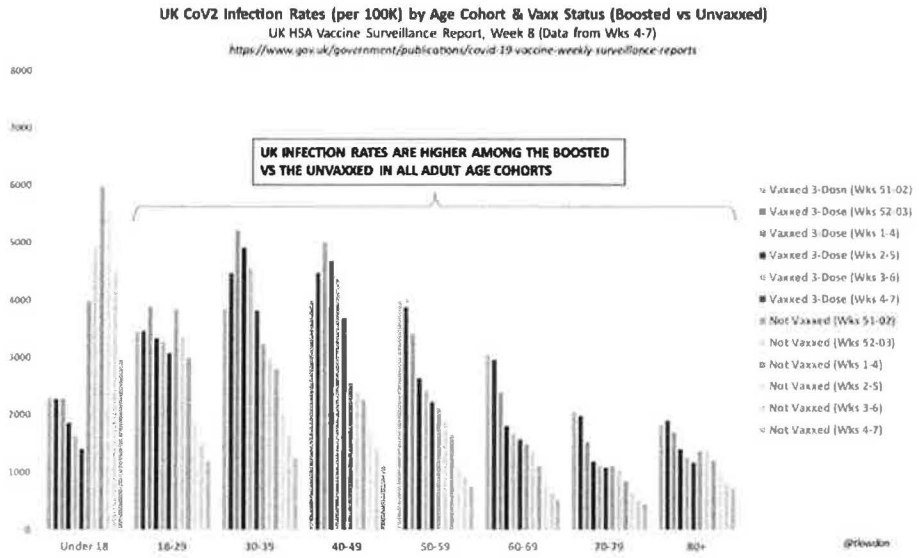


Consolidating fully vaccinated and boosted individuals into a "2 or more doses" category to correspond to the CDC data above, we see the following across all age cohorts from Walgreens:

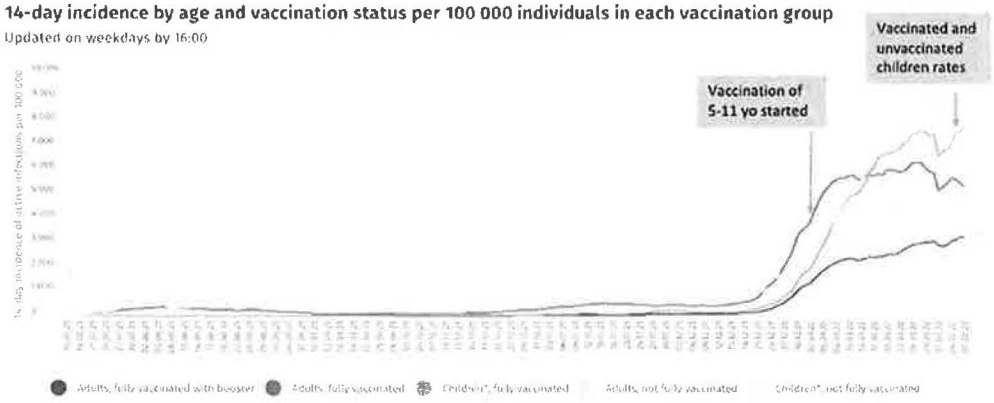


These high positivity rates in vaccinated individuals are duplicated across multiple countries.

The United Kingdom[10]:



Iceland:



[10] https://www.gov.uk/government/publications/covid-19-vaccine-weekly-surveillance-reports

And the high infection rates in vaccinated, and even near universally boosted populations is evident in multiple local data sets such as the University of California campuses.

The University of California at Irvine:[11]

Daily snapshot: 5/27/2022 6:04:04 AM

Positive cases reported yesterday

57

All Students: 53
Students in Campus Housing 36
Students not in Campus Housing 17
Staff and Faculty/Academics: 4

Cumulative positive cases

5,426

All Students: 4,563
Students in Campus Housing: 2,336
Students not in Campus Housing: 2,227
Staff and Faculty/Academics: 863

Total number of people testing positive starting September 5, 2021

Active positive cases

429

All Students: 390
Students in Campus Housing 256
Students not in Campus Housing 134
Staff and Faculty/Academics: 39

Those who are currently recuperating

Cumulative recovered cases

4,997

All Students: 4,173
Students in Campus Housing: 2,080
Students not in Campus Housing: 2,093
Staff and Faculty/Academics: 824

Those cleared to return to normal daily activity

Isolation and quarantine beds available

257

Out of 362 total beds

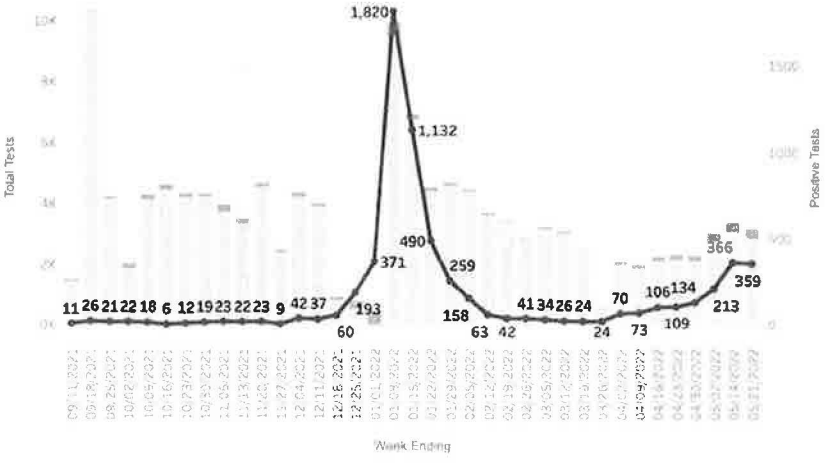
Vaccination and Booster Data

	% Vaccinated	% Boosted*	Total Vaccinated	Total Population
All Students	98%	97%	33,711	34,484
Students in Campus Housing	99%		14,074	14,214
Students not in Campus Housing	97%		19,637	20,270
Staff and Faculty/Academics	95%	99%	6,683	7,007

* % boosted is a subset of total vaccinated who are eligible to be boosted

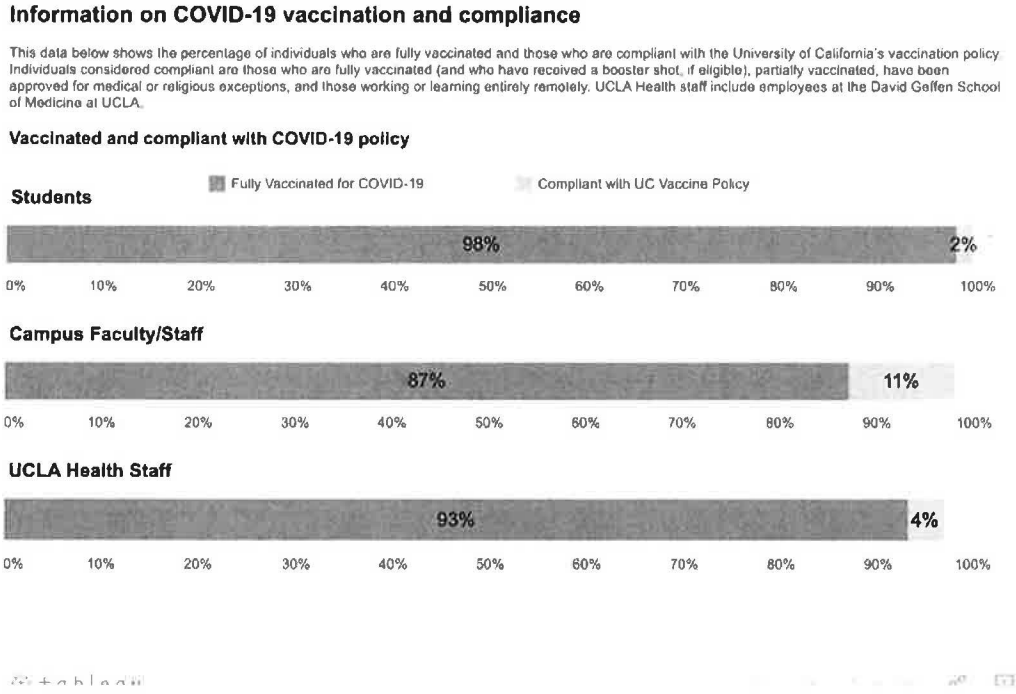
Symptomatic and asymptomatic testing

Testing since September 5, 2021. The following chart combines asymptomatic and symptomatic results.

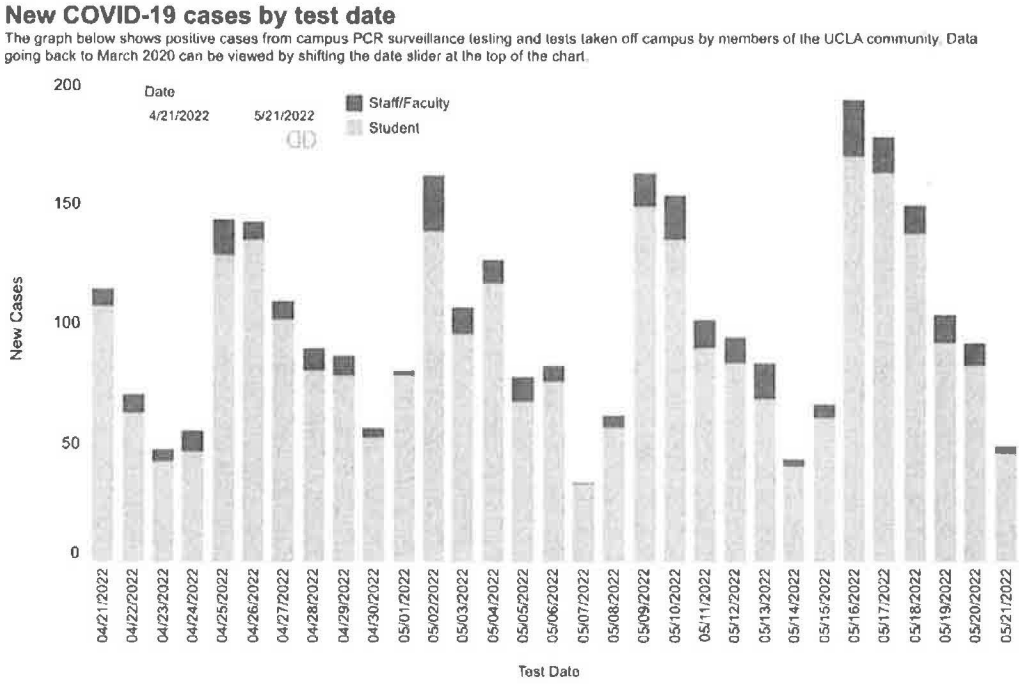


[11] https://uci.edu/coronavirus/dashboard/index.php

University of California at Los Angeles:[12]



[12] https://covid-19.ucla.edu/confirmed-cases-of-covid-19-among-the-ucla-campus-community/



Coming back to Danish research on transmission with the BA.2 Omicron variant (dominant now) versus the BA.1 Omicron variant (dominant through the winter of 2021-22), they noted:[13]

> Both unvaccinated, fully vaccinated and booster-vaccinated individuals had a higher susceptibility for BA.2 compared to BA.1, indicating an inherent increased transmissibility of BA.2 (Table 3). However, the relative increase in susceptibility was significantly greater in vaccinated individuals compared to unvaccinated individuals (appendix Figure 6, which points towards immune evasive properties of the BA.2 conferring an even greater advantage for BA.2 in a highly vaccinated population such as Denmark. Because previous studies of the Omicron VOC has focused on the BA.1 (Pearson et al., 2021; Planas et al., 2021), new studies are needed to further investigate these properties for BA.2.

[13] https://www.medrxiv.org/content/10.1101/2022.01.28.22270044v1

Vaccine mandates for COVID-19 vaccines were an ill-conceived policy more than a year ago. As noted by Dr. Patrick Moore during the original Pfizer FDA review meeting, "FDA did not ask in its guidance and Pfizer has presented no evidence in its data today that the vaccine has any effect on virus carriage or shedding" (page 342 of the transcript).[14]

Having said the above, it is well past time to reconsider our approach to COVID-19 especially as it pertains to COVID-19 vaccine mandates even if one truly believes that *any* reduction in transmission is demonstrable. When considering the susceptibility of the general population to COVID-19 in May of 2022, at least 97% of Americans are no longer immune-naïve to SARS-CoV-2 through either vaccination, infection, or hybrid immunity.[15] As noted by FDA voting member Dr. Paul Offitt, it is clear that neither vaccination or mass testing will stop COVID-19, but both vaccination and prior infection will confer resistance to severe disease.[16] This "herd resistance to severe disease " will not confer iron-clad protection from an "infection" moving forward, but it's

[14] https://www.fda.gov/media/144859/download (page 342)
[15] https://covid19serohub.nih.gov/
[16] https://www.inquirer.com/health/expert-opinions/covid-19-pandemic-immunity-boosters-normal-20220304.html?

main value will be protection from severe disease and there is historical precedent for this belief.[17] By July 13th, 2022, with likely well over 97% of Americans (was 97% through February 18th, 2022) falling into a category of prior vaccination and/or prior infection, as a population, we have achieved as much meaningful population level protection as is possible. Moving forward, every individual, based upon their individual age, metabolic risks, immune status, and personal preferences, will have to decide how best to proceed with future vaccine doses or therapeutics.[18]

Influenza

This brings us full circle to Influenza as the parallels are dramatic. Both are RNA viruses of roughly the same size, both are transmitted by droplets and aerosols, and the impacts of vaccination are quite similar. COVID-19 has followed the path of Influenza: now, as with influenza, cases of COVID-19 will continue to appear, but the number and severity of those infections will be significantly reduced even while neither vaccination or prior infection represents an impenetrable shield to

[17] https://www.eurekalert.org/news-releases/694958
[18] https://www.nature.com/articles/s41574-021-00608-9

subsequent infection.[19,20] In fact, a 2018 study positively correlated amount of virus in exhaled breath with vaccination status thereby suggesting that in the study population, those vaccinated with the Influenza vaccine were spreading more viral particles.[21] It is well established that the benefits of Influenza vaccination extend to the individual receiving the vaccination which is traditionally why Influenza vaccination in health care settings has been recommended and not mandated (until recently at some institutions). Indeed, a 2017 study established that patient benefit from healthcare worker was not established:

> "The impression that unvaccinated HCWs place their patients at great influenza peril is exaggerated. Instead, the HCW-attributable risk and vaccine-preventable fraction both remain unknown and the NNV to achieve patient benefit still requires better understanding. Although current scientific data are inadequate to support the ethical implementation of enforced HCW influenza vaccination, they do not refute approaches to support voluntary vaccination or other more broadly protective practices, such as staying home or masking when acutely ill." [22]

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[19] https://www.eurekalert.org/news-releases/694958

[20] https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00180-4/fulltext

[21] https://www.pnas.org/doi/10.1073/pnas.1716561115

[22] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0163586

This has led Dr. Michael Osterholm, formerly a member of the Biden Administration's COVID Task Force to state:

> "We have to make public health recommendations based on good science," Osterholm added, "but we do not have the justification to take punitive action against healthcare workers if they don't get vaccinated [for Influenza]." [23]

"Sterilizing Vaccines" and Mandates

When we refer to "sterilizing vaccines", we are referring to vaccines that confer both protection from infection thereby effectively eliminating infection risk as well as providing protection from severe illness. Traditionally, as canonical examples of "sterilizing vaccines", we consider the Measles/Mumps/Rubella (MMR) vaccine as it pertains to Measles and the Hepatitis B vaccine. Measles, like Influenza and SARS-CoV-2 (the virus that causes COVID-19) are respiratory viruses. Measles transmission while through droplets and aerosols, is more droplet mediated than with COVID-19 or Influenza, and yet remains highly contagious. In the case of Measles and Hepatitis B, there is a major component of the infection that is bloodborne (unlike SARS-CoV-2 or

[23] https://www.cidrap.umn.edu/news-perspective/2017/01/health-worker-flu-vaccine-data-insufficient-show-protection-patients

Influenza) such that blood-borne vaccine or infection induced antibodies can perform a pivotal role in preventing infection. But even in the context of Measles and Hepatitis B vaccines, "sterilizing" is a relative term.

Numerous studies have shown that those vaccinated against Measles can develop infections, even as the primary value remains protection from severe illness. In a recent 2018 study of an outbreak in a French Psychiatric ward, 14% of fully vaccinated index cases from a primary unvaccinated case developed Measles. 2 of the cases had 2 Measles vaccinations and one even had vaccination with a prior infection in the preceding 6 years.[24] A less contained outbreak in New York was traced to a vaccinated index case.[25]

All of this said, an outbreak of Measles in the Marshall Islands demonstrated that non-vaccine eligible infants were more likely to be infected as secondary contacts than adults (46% versus 13%).[26] In this outbreak, the largest in the United States or associated area in more than a decade, 41% of cases were reported to have been previously vaccinated.

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[24]https://journals.lww.com/pidj/FullText/2019/09000/Measles_Transmission_in_a_Fully_Vaccinated_Closed.27.aspx

[25] https://academic.oup.com/cid/article/58/9/1205/2895266

[26] https://pubmed.ncbi.nlm.nih.gov/16392073/

Given that Measles vaccine is not recommended under 12 months of age, the biggest lesson of the Marshall Islands outbreak was the susceptibility of vulnerable non-vaccine eligible populations. It is thought that 90% vaccine coverage is required for the prevention of such outbreaks.

In the case of Hepatitis B, transmission is through body fluid contact. Vaccination, or infection, followed by documented threshold antibody levels is highly effective in preventing infection and transmission. Once again, "sterilizing immunity" in this context remains "relative" with documented Hepatitis B cases in previously vaccinated individuals. In one study, roughly 10% of previously vaccinated individuals with no evidence of prior infection had detectable Hepatitis B virus through DNA-testing suggesting evidence of an undetected "breakthrough" infection.[27] Once again, as with protection from a Measles vaccination, the benefit accrued to the vaccinated individual is substantial. In East Asian countries, Hepatitis B is endemic (spreads at baseline through the population). With the advent of universal Hepatitis B vaccination of newborns in Taiwan, the infant mortality rate from

[27] https://journals.lww.com/md-journal/fulltext/2016/12060/hepatitis_b_viremia_in_completely_immunized.92.aspx

hepatitis B dropped by 3-fold and severe hepatitis almost disappeared in older children.[28,29,30]

Summary

While we can establish significant distinctions between "sterilizing vaccines" and vaccines such as the ones for COVID-19 and Influenza, it remains the case that the main benefit of vaccination is accrued to the individual receiving the vaccination. For vaccines such as the COVID-19 and Influenza vaccines where there is minimal prevention of subsequent infection and transmission, it's extremely difficult to supplant individual bodily autonomy particularly at threat of unemployment or violation of one's religious beliefs.

However, for "sterilizing vaccines", even while they do not absolutely prevent subsequent infection, clearly demonstrated reduction in transmission with high community vaccination rates requires more consideration than one's personal autonomy. Specifically, nuance is required when considering populations that are at risk of disease, but are

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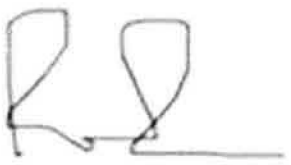
[28] https://pubmed.ncbi.nlm.nih.gov/11562612/
[29] https://pubmed.ncbi.nlm.nih.gov/14752823/
[30] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3630933/

not eligible, either through age or circumstance, to receive a particular "sterilizing vaccine". In these cases, caregivers who do not accept such "sterilizing vaccines" where said vaccination can markedly attenuate transmission when community vaccine coverage is more than 90%, may need to accept special precautions when caring for vulnerable populations. While one might argue that these precautions should be entertained regardless of vaccination status, community vaccination rates for such "sterilizing vaccines" will affect the risk of infection and transmission irrespective of any one individual's vaccination status. These special precautions may include, but are not limited to, use of fit-tested N95 masking, enhanced barrier precautions, and even surveillance testing.

I declare under penalty of perjury, under the laws of the State of Montana, that the foregoing is true and correct.



Ram Duriseti MD, PhD
July 15th, 2022

Ram Duriseti, M.D., Ph.D.
(650) 521-4517
ramduriseti@gmail.com

Educational Background:

Engineering:

•9/01-5/07: Doctoral degree from the Stanford University School of Engineering with a concentration in Decision/Risk Analysis, Machine Learning, and Clinical Decision Support. Coursework included Decision and Risk Analysis, Probability and Statistical Inference, Bayesian Networks, Machine Learning, Computer Science, and Clinical Informatics. Funded through a VA Medical Informatics Fellowship.

- Computing Background: C++, Java, Matlab, C, Ruby On Rails, Javascript and HTML with Ajax, Drools (JBoss Rules Engine), controlled medical terminology deployment (IMO services, SNOMED-CT, RxNorm, and other UMLS resources), Apelon server deployment, LISP, PostGreSQL, MySQL, JBoss application server, UNIX environment, Visual Basic (Excel Modules), Git, Subversion and Mercurial version control

Medical and Undergraduate:

•11/97-11/2001: Residency training in Emergency Medicine at Stanford Medical Center.
•5/96: M.D. with highest honors, University of Michigan Medical School
•6/92: B.S. in Biololgy, and B.A in Political Economy, with distinction Stanford University.

Select Relevant Employment Experience:

11/00 – Present: Clinical Associate Professor, Stanford Emergency Department. Contacts: Dr. Bernard Dannenberg and Dr. Matthew Strehlow. Numbers available upon request.
3/01- Present: Mills Peninsula Emergency Medical Associates shareholder. President and CEO until 6/2017
6/08 – Present: Founder, CEO, and Product Engineer (principle algorithm and product design architect) for ShiftRx, L.L.C. ShiftRx provides the ShiftGen service that provides a cloud based enterprise workforce management tool. Key elements: machine learning algorithms, schedule optimization, workforce management, revenue cycle management with payroll integration, Java, Ruby on Rails, MySQL, SaaS on ec2.
10/08 – Present: Special consultant and subject matter expert to Sutter Health for Epic EHR implementation. Provided technical design for the billing extracts to migrate clinical information into a file sharing framework for billing companies supporting Sutter Emergency Medicine groups. Contacts: Multiple. Numbers available upon request.
4/15 – 3/2017: CEO and subsequently CTO and CMO of LifeQode Inc. which provides the Lifesquare product. Helped craft and secure 4 different patents, with continuations, around the central business processes for the product. Contacts: Larry Leisure and Steve Shulman. Numbers available upon request.
7/09 – 10/09: Technical consultant to Rise Health, Inc.. Contacts: Eric Langshur, Forrest Claypool, and Inder-Jeet Gujral. Numbers available upon request.
1/07 – 9/08: Chief Medical Officer and Director of Medical Informatics for Enfold, Inc. Responsibilities include design and implementation of intelligent medical functionality and a taxonomy engine as well as oversight of medical content driving the system. Implementation

details: Java, Ruby on Rails, Drools, Apelon Server, Oracle 10g Database, MySQL. Contacts: Inder-jeet Gujral, Kimberly Higgins-Mays. Numbers are available upon request.
10/06 – 3/08: Medical Informatics Director Working Group Stanford University Hospitals and Clinics CIS Initiative. Particular emphasis on hand held technology integration into the Epic Initiative and organizing patient encounter level reportable data on clinical documentation events. Contacts: Kevin Tabb, President and CEO Beth Israel Deaconess Medical Center. Contact information is available upon request.
6/05 –12/06: Design and implementation of an attribute matching expert system in Java as a consultant to Wellnet Inc. Implemented in a Java environment with Hibernate DBMS and MySQL. Contacts: Kimberly Higgins-Mays. Number available upon request.

Select Research Experience:
7/11-Present: Design and implementation of a computational model for stochastic stimulation of the cost-effectiveness of various strategies to diagnose pediatric appendicitis (manuscript in progress).
10/05-Present: Design and implementation of an asymmetric cost Support Vector Machine to evaluate a large clinical database on chest pain patients presenting to the University of Pennsylvania Hospital Emergency Department (manuscript in progress).
09/02-9/04: Medical Informatics Fellow, Palo Alto Veteran's Administration Hospital.
04/03-Present: Development of Bayesian decision network for evaluation of the clinical utility of the quantitative Vidas ELISA Ddimer Assay. Published work listed.
02/04-Present: Bayesian decision network implementation modeling reasoning in the clinical domain of chest pain and associated pathology in the Emergency Department.
6/05-3/06: Using portable digital devices to generate a standard electronic medical record that can be downloaded directly to a relational database to facilitate data mining for prospective clinical research.
11/99 – 4/00: Retrospective chart review to examine the incidence of electrolyte and cardiac enzyme abnormalities in patients presenting to the Stanford Emergency Department with Supraventricular Tachycardia.

Select Administrative Experience:
6/09 – Present: CEO and Founder of ShiftRx, LLC
6/09 – Present: Regional Information Services Steering Committee for Sutter Health
6/08 – 6/18: President of CEO of Mills Peninsula Emergency Medical Associates
9/12 – 3/17: Acting CMO and CEO of Lifesquare, Inc.
6/07 – 9/08: Chief Medical Officer and Director of Medical Informatics at Enfold, Inc.
5/05-9/08: Member of Medical Informatics Director Working Group and RFP phase of evaluation for the Epic initiative at Stanford University Hospitals and Clinics
4/05-6/06: Served on the Mills-Peninsula Health Information Management and Medical Records Committee.

Current Volunteer Activities
3/22 – Present: Board of Director of Restore Childhood which is a non-profit focused on research initiatives quantifying risks to children in schools in the 'COVID Era". The goals are both legal and scientific. The scientific goal is to generate novel research and support mitigation measures that are both effective and maintain in person education.

EXHIBIT A

12/21 – Present: Co-author of Urgency of Normal. We are a group of physicians focused on collating and presenting data as it pertains to children and COVID. We help facilitate safe school openings.
Guest Lecturer at the Wharton School of Business (University of Pennsylvania) 2007/2008/2009 for health economics and information technology course

Select Honors and Distinctions:

- Guest Lecturer at the Wharton School of Business (University of Pennsylvania) 2007/2008/2009 for health economics and information technology course
- VA Medical Informatics Fellowship
- Alpha Omega Alpha Medical Honor Society
- Graduation with Distinction from the University of Michigan Medical School (top 5%)
- Recommended for Graduation with Distinction from Stanford University
- National Merit Scholarship Recipient
- Telluride Foundation Fellow

Select Papers and Publications:

- Lowe, T., Brown, I., Duriseti, R. "Emergency Department Access During COVID-19: Dis parities in Utilization by Race/Ethnicity, Insurance, and Income", Western Journal of Emergency Medicine; April, 2021

- Duriseti, R., Brandeau M. "Cost-Effectiveness of Strategies for Diagnosing Pulmonary Embolism Among Emergency Department Patients Presenting with Undifferentiated Symptoms", Annals of Emergency Medicine; October, 2010

- Duriseti, R., Wu, T. "Gastrointestinal introduction and abdominal pain – Pediatric Abdominal Pain in the Emergency Department", A Practical Guide to Pediatric Emergency Medicine, Cambridge University Press, Cambridge, 2010

- Duriseti, R. "Musculoskeletal Trauma: fractures", A Practical Guide to Pediatric Emergency Medicine, Cambridge University Press, Cambridge, 2010

- Duriseti, R. "Using Influence Diagrams in Cost Effectiveness Analysis for Medical Decisions", Optimization in Biology and Medicine, Auerbach Press, New York, 2008

- Duriseti, R. "Non-Bayesian Classification to Obtain High Quality Clinical Decisions", Optimization in Biology and Medicine, Auerbach Press, New York, 2008

- Duriseti, R., Shachter R., Brandeau M. "Implications of a Sequential Decision Model on the Use of Quantitative D-Dimer Assays in the Diagnosis of Pulmonary Embolism", Academic Emergency Medicine; July, 2006

- Duriseti R, VanderVlugt T. Paroxysmal supraventricular tachycardia is not associated with clinically significant coronary ischemia. ACEP Abstracts. ACEP Scientific Assembly 10/2001

EXHIBIT A

•VanderVlugt T., Duriseti R. Electrolyte findings in patients with paroxysmal supraventricular tachycardia. ACEP Abstracts. ACEP Scientific Assembly 10/2001

•Contributing Editor for Trauma Reports for the topic, "Trauma in Pregnancy"; published 2/2001

•Duriseti R. Cost Effective Management of Common Infections in the Emergency Department. Resident Reporter. Wyeth Ayerst Resident Scholars Program. March, 2000

Select Professional Lectures:

- Commonly Encountered Statistical Concepts in the Emergency Medicine Literature
- Medical Decision Making, Clinical Information Systems, and Cost Control: Complexity Collides with Uncertainty

Previous Expert Witness Testimony

- *Elijah Brown, et al. v. Mills-Peninsula, et al.*, No. CIV536321 (Cal. Super. Ct. Cty of San Mateo 2015)
- *Julia Sullivan v. The Superior Court of Santa Clara*, No. 18FL001837 (Cal. Super. Ct. Cty of Santa Clara 2018)
- *UNIFYSCC, et al. v. Sara H. Cody, et al.*, No. 22-cv-01019-BLF (N.D. Cal. 2022)
- *Vincent Tsai, et al. v. County of Los Angeles*, No. 21STCV36298 (Cal. Super. Ct. Los Angeles Cty 2021)
- *Jennifer Guilfoyle et al. v. Austin Beutner et al.*, No. 2:2021-cv-05009-VAP (C.D. Cal. 2021)

EXHIBIT A

Exhibit 8

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Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

MONTANA MEDICAL ASSOCIATION, et al.,

Plaintiffs,

and

MONTANA NURSES ASSOCIATION,

Plaintiff-Intervenors,

v.

AUSTIN KNUDSEN, et al.,

Defendants.

Case No. CV 21-00108-DWM

PLAINTIFFS' FOURTH SUPPLEMENTAL RESPONSES TO DEFENDANTS' FIRST COMBINED DISCOVERY REQUESTS

Plaintiffs submit the following supplemental answers/responses to Defendants' First Combined Discovery Requests dated June 29, 2022.

These answers/responses are prepared and submitted in accordance with Federal Rules of Civil Procedure 26, 33, 34, and 36. Plaintiffs do not recognize or accept any obligation to supplement answers/responses to discovery requests except as required by Federal Rule of Civil Procedure 26(e). The preface included in these discovery requests is not within the express or implied provisions of the Federal Rules of Civil Procedure and, as such, has been disregarded in preparing these answers/responses.

In the event Plaintiffs inadvertently or otherwise produce copies of documents that are subject to protection from discovery under the doctrines of attorney-client privilege, work-product, trade secrets, confidentiality, proprietary or confidential business or commercial information, or are not relevant and not reasonably calculated to lead to the discovery of the admissible evidence, any production herewith shall not be deemed a waiver of such protection or any subsequent obligation to use for admissibility in any proceedings herein.

INTERROGATORY NO. 5: In Paragraph 25 of the Second Amended Complaint, Individual Plaintiffs allege that they must "avoid or minimize contact" with "persons who carry or may carry the COVID-19 virus" and must "avoid commercial and professional establishments" that "fail to take steps to minimize the spread of the virus and other common viruses and germs" and must avoid establishments that "employ unvaccinated workers" or are unable to "take

necessary measures to protect against preventable diseases." Please describe in detail how you define these quoted phrases from Paragraph 25 of the Second Amended Complaint.

ANSWER: The phrases quoted in the response are defined as to their ordinary meaning. As additional explanation, individuals who are vulnerable due to age, disability, or health condition are more at risk of contracting and being harmed by vaccine-preventable diseases. These individuals are required to take particular precaution to avoid contracting vaccine-preventable diseases. This applies not only to COVID during the current pandemic, but to all infectious diseases.

For Mark Carpenter specifically, as a kidney transplant patient, he was given a significant amount of guidance prior to the transplant and afterwards regarding the risks of infections because of immunosuppressants. This started back in 2016 when he applied for a kidney transplant and the guidance is ongoing. This included his entire transplant team at Virginia Mason Hospital in Seattle, his primary care physician in Missoula, his nephrologist in Missoula, his infectious disease specialist in Missoula, and the Missoula County Health Department where he received a large number of vaccinations strongly recommended by his various medical providers. People on immunosuppressants are given guidance to the extent of avoiding things like salad bars due to the risk of infection for diseases

like Hepatitis B. In order to protect himself during the pandemic, he did extensive research on his own following clinical studies at John Hopkins and elsewhere. This is how he discovered that the vaccines might not produce antibodies for him and what levels of antibodies are expected to provide protection. For these reasons, he has not attended large gatherings (conferences, trade shows, sporting events, festivals, concerts, or weddings) since the pandemic began. Since March 2020, he has lived at his remote cabin on Salmon Lake and kept his interactions to a very small group of friends and family who were fully vaccinated and exercised caution.

For Wally Page, he avoided seeing people and establishments who disregarded masking and vaccination recommended by health care professionals. Jo Page limited places she visited to healthcare establishments, where providers masked and followed distancing protocols.

Cheyenne Smith was pregnant during the pandemic and exercised caution when in public. Pat Appleby also exercised caution when leaving the house or going to the grocery store.

FIRST SUPPLEMENTAL ANSWER: Plaintiffs provide the following additional information from each individual Plaintiff.

Additional information for Wally and Jo Page

For Wally, frequent trips to health care providers are not optional and he expects that his medical providers do him no harm. They mask and keep a clean work environment and he naturally assumed their vaccinations were a work requirement. With his cancer diagnosis, he has had to be very cautious. He felt some of the times he was at most risk of catching something included going to the emergency care waiting room where very sick patients waited for treatment. He knew that many of the sickest with COVID ended up being treated at emergency care before admission to the hospital. He has had to visit the chemotherapy infusion room over 100 times. Not knowing whether all individuals were vaccinated, he has had to be very cautious and he feels lucky that he did not catch COVID from someone there while he was receiving those treatments (though did contract COVID later).

Jo was diagnosed with breast cancer in 2019. As she met with different doctors, including primary care, oncologist, surgeons, and radiologists, she learned from them how important it was to keep herself safe from crowds, public areas, and exposures to anything that could penetrate her immune compromised system. She has a very active family and once the pandemic surfaced, she and her family became isolationists. They did not attend athletic events, weddings, any organization meetings, concerts, or the like. Her family would come by and talk to Wally and Jo from the yard just so they could see them and vice versa. Then

Wally was diagnosed with Non-Hodgkin's Lymphoma and Multiple Myeloma. At this point, Jo did the shopping which was mostly done via the internet and curb side services at grocery stores. Her contact with friends and family was mostly by phone and social networking. She did get all the immunizations offered for COVID-19.

Jo and Wally were extremely cautious with masking and personal contact. Gradually, their families came to visit, still masking. As of late, they have started seeing friends in small groups and still masked. They finally felt comfortable attending some of their grandchildren's events. And then Jo and Wally both contracted COVID. They are thankful they were immunized and they both recovered from COVID. They did receive the antiviral treatments as part of their treatment for COVID. Then they went back to being more cautious again.

Additional information for Pat Appleby:

During 2020, Pat worked in Billings at a plant nursery job where +/- 90% of the work was outdoors and masks and social distancing were nonetheless required. That seasonal employment ended at the end of November, and she thereafter hunkered down at home in the Bitterroot Valley with family going out as little as possible. She has many friends in her age group with health concerns as well and they freely discussed the need for vaccinations and precautions.

During the spring of 2021, vaccinations became available and her and her family were all fully vaccinated. By the time vaccine waiting periods were complete they were continuing to restrict activity but feeling less intimidated about going out and about. They did have out of state friends visit during the summer, but they were vaccinated prior to travel.

Pat and her husband were working a combination of in person and at home throughout 2020 and 2021. Pat's husband's employer required staff to wear masks and reduced customer contact as much as possible. They also encouraged customers to wear masks when interacting with company employees. Many of his customers were unwilling to protect themselves and others. By November 2021, her husband tested positive for COVID, and she tested positive a few days later. Fortunately for her, the illness was not severe and she recovered. But as the months go on, she is feeling many symptoms of what is now being called "Long Covid."

As for Cheyenne Smith:

Cheyenne has been immunocompromised since her diagnosis of Juvenile Rheumatoid Arthritis since 1996. She has always been cautious of her surroundings. Relying on immunosuppressants to live day to day, she has always been advised that she was at higher risk for infections and illnesses. Growing up,

she was constantly reminded to wash her hands and avoid any children that might be sick in school.

She loves her work as a dental hygienist. Upon getting accepted into hygiene school she was required to receive many vaccinations in order to attend. She has always assumed that all healthcare workers are required to receive vaccinations to go through school. As a hygienist, she believes becoming vaccinated is a measure to protect herself, her family, as well as her patients.

COVID-19 brought upon a whole new level of terror into Cheyenne's life. COVID-19 was so new, scary and unknown that she was terrified to go back to work. In late fall 2020, she found out she was pregnant. She struggled to get pregnant and once she was able to conceive, she was advised to be extremely cautious by her OBGYN, and was strongly advised to get vaccinated against COVID19 by both her OBGYN and her rheumatologist.

Cheyenne got vaccinated for COVID-19 when cleared for emergency use for healthcare workers, and at 5 weeks pregnant. She got vaccinated to protect herself, her growing baby, her husband and her patients. She believes this is the right thing to do as a healthcare worker, you protect yourself and you protect those you are caring for.

Every rheumatology visit, every ultrasound, and every prenatal visit she masked and followed all the guidelines recommended by her medical professionals to avoid as best she could the possible risk of infection.

Following the birth of her child, she now had a newborn who had no immune system and was unable to get vaccinated against COVID-19. She evermore trusted the healthcare workers were getting vaccinated to protect their patients, even the littlest patients.

As for Mark Carpenter:

Mark's primary care doctor and nephrology teams were adamant pre- and post-transplant about being up to date on all vaccinations and other preventative healthcare tasks. Mark received many of his vaccinations at the Missoula County Health Department and they also strongly stressed how important vaccinations were. Other things Mark did to reduce risk:

- Ordered groceries online with a specific pickup time where you park and they bring groceries to your car.
- Order more things online as opposed to going to local stores.
- Ordered food online for pickup/delivery as opposed to dining in.
- Did not visit any family members or friends who were not fully vaccinated and didn't wear masks or take precautions to disinfect surfaces. When socializing most activities were outdoors and tried to implement social distancing whenever possible.
- Canceled pre-planned vacation travel like annual family ski trips.

INTERROGATORY NO. 12: Please explain in detail what steps, if any, individual Plaintiffs took prior to May 7, 2021 to assess the vaccination or

immunity status of employees or personnel at any commercial or professional establishment before entering it.

ANSWER: Plaintiffs object that this request is overly broad, unduly burdensome and not limited to a discreet timeframe. As to the non-objectionable portion of the request, in general, prior to the COVID pandemic, the individual plaintiffs did not believe vaccination was an issue, due to the fact that vaccinations were a common requirement for the military, public schools, and daycares. Individual plaintiffs were unaware of the magnitude of the anti-vaccination movement prior to the pandemic. Mark Carpenter, for example, assumed most individuals were vaccinated, as vaccination status had never previously been a political issue and vaccinations were a common requirement of people proceeding through the public school system. In healthcare settings, Mark Carpenter assumed vaccination was a requirement of employment to protect patients, given that vaccinations were mandated for public schools and daycares.

FIRST SUPPLEMENTAL ANSWER: Please see the first supplemental answer to Interrogatory No. 5.

REQUEST FOR ADMISSION NO. 8: Please admit that the Montana Department of Health and Human Services has never required staff vaccination as a condition of participation in Medicaid.

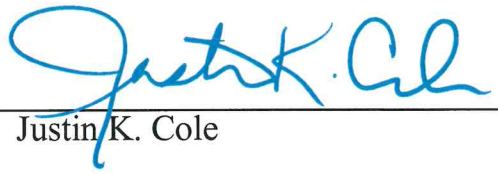
RESPONSE: Plaintiffs object that this request is overly broad, unduly burdensome, argumentative, assumes inaccurate facts, and seeks information not in the possession of Plaintiffs. Plaintiffs are unable to answer this request as Montana DPHHS is not responsible for establishing the conditions of participation for Medicaid.

FIRST SUPPLEMENTAL RESPONSE: Subject to the objections and response set forth in the initial response, Plaintiffs deny this request as written. The conditions for participation in Medicare and Medicaid are set by the Centers for Medicare and Medicaid Services, set forth in Title 42 of the Code of Federal Regulations ("CFR"). DPHHS may not set standards for the quality of care that are inconsistent with the requirements in Title 42 of the CFRs. *See* Mont. Code Ann. § 53-6-106(3). Furthermore, as a condition of participation in the Montana Medicaid program, all providers are required by DPHHS regulations to comply with all applicable state and federal statutes, rules and regulations, including but not limited to the federal regulations and statutes found in Title 42 of the CFR and the USC governing the Medicaid program. Admin. R. Mont. 37.85.401. As such, Montana regulation would, at a minimum, require participating facilities to comply with the CMS Conditions of Participation, and would specifically require hospitals to comply with 42 CFR 482.41 and 482.22.

DATED this 19th day of August, 2022.

Attorneys for Plaintiffs:

GARLINGTON, LOHN & ROBINSON, PLLP

By 

Justin K. Cole

CERTIFICATE OF SERVICE

I hereby certify that on August 19, 2022, a copy of the foregoing document was served on the following persons by the following means:

_____ Hand Delivery
1-3 Mail
_____ Overnight Delivery Service
_____ Fax (include fax number in address)
1-3 E-Mail (include email in address)

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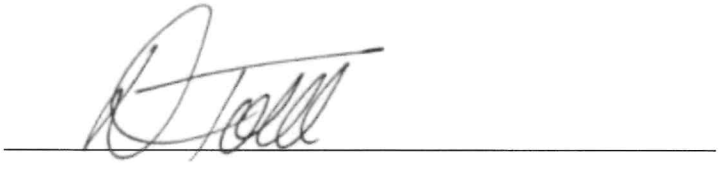

Exhibit 9

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

MONTANA MEDICAL ASSOCIATION, et al., Plaintiffs, and MONTANA NURSES ASSOCIATION, Plaintiff-Intervenors, v. AUSTIN KNUDSEN, et al., Defendants.	Case No. CV 21-00108-DWM PLAINTIFFS' RESPONSES TO DEFENDANTS' FIRST COMBINED DISCOVERY REQUESTS

Plaintiffs submit the following answers/responses to Defendants' First Combined Discovery Requests dated June 29, 2022.

These answers/responses are prepared and submitted in accordance with Federal Rules of Civil Procedure 26, 33, 34, and 36. Plaintiffs do not recognize or accept any obligation to supplement answers/responses to discovery requests except as required by Federal Rule of Civil Procedure 26(e). The preface included in these discovery requests is not within the express or implied provisions of the Federal Rules of Civil Procedure and, as such, has been disregarded in preparing these answers/responses.

In the event Plaintiffs inadvertently or otherwise produce copies of documents that are subject to protection from discovery under the doctrines of attorney-client privilege, work-product, trade secrets, confidentiality, proprietary or confidential business or commercial information, or are not relevant and not reasonably calculated to lead to the discovery of the admissible evidence, any production herewith shall not be deemed a waiver of such protection or any subsequent obligation to use for admissibility in any proceedings herein.

INTERROGATORY NO. 1: Please identify each and every person who prepared or assisted in the preparation of answering these discovery requests.

ANSWER: The following individuals prepared or assisted in preparing these responses, with the assistance of counsel:

1. Jean Branscum
2. Kirk Bodlovic

3. Karyn Trainor

4. Tammy Powers

5. Meghan Morris

6. John O'Connor

7. Mark Carpenter

8. Pat Appleby

9. Diana Jo Page

10. Wallace L. Page

11. Cheyenne Smith

INTERROGATORY NO. 2: Please identify each and every person known by you to have knowledge of the facts, events, and circumstances related to this action, including a brief summary of the facts, events, and circumstances known by each person.

ANSWER:

1. Jean Branscum or other representatives of Montana Medical Association ("MMA"), c/o Garlington, Lohn & Robinson, PLLP. Jean Branscum has knowledge regarding the impact of the law related to MMA members, impact of the law regarding patient care and employment, hiring, accommodations, attempted compliance efforts, harm caused by the law, and additional information regarding the facts set forth in the Second Amended Complaint and Defendants'

defenses, as well as infectious disease prevention. Ms. Branscum may also have knowledge regarding patient care and treatment and professional obligations of medical practitioners.

2. John O'Connor, Karl Westenfelder, M.D., or other representatives of Five Valleys Urology ("Five Valleys"), c/o Garlington, Lohn & Robinson, PLLP. Five Valleys representatives have knowledge regarding the impact of the law related to Five Valleys and offices of private physicians, impact of the law in various clinical settings, impact of the law regarding patient care and employment, hiring, accommodations, attempted compliance efforts, harm caused by the law, Five Valleys' policies and procedures, and additional information regarding the facts set forth in the Second Amended Complaint and Defendants' defenses. Five Valleys representatives may also have knowledge regarding CDC guidelines, as well as infectious disease prevention. Five Valleys representatives may also have knowledge regarding patient care and treatment and professional obligations of medical practitioners. Please also see Plaintiffs' expert disclosures.

3. Joyce Dombrowski, Kirk Bodlovic, Karyn Trainor, Tammy Powers or other representatives of Providence Health and Services ("Providence"), c/o Garlington, Lohn & Robinson, PLLP. Providence representatives have knowledge regarding the impact of the law related to Providence, offices of private physicians, hospitals, and other various clinical settings, impact of the law regarding patient

care and employment, hiring, accommodations, attempted compliance efforts, harm caused by the law, Providence's policies and procedures, and additional information regarding the facts set forth in the Second Amended Complaint and Defendants' defenses. Providence representatives may also have knowledge regarding CDC, OSHA, and CMS guidelines, including but not limited to the CMS COVID vaccination mandate, well as infectious disease prevention. Providence representatives may also have knowledge regarding patient care and treatment and professional obligations of medical practitioners. Please also see Plaintiffs' expert disclosures.

4. Meghan Morris, Dirk Gottman, M.D., or other representatives of Western Montana Clinic ("Clinic"), c/o Garlington, Lohn & Robinson, PLLP. Clinic representatives have knowledge regarding the impact of the law related to Clinic, offices of private physicians, and other various clinical settings, impact of the law regarding patient care and employment, hiring, accommodations, attempted compliance efforts, harm caused by the law, Clinic's policies and procedures, and additional information regarding the facts set forth in the Second Amended Complaint and Defendants' defenses. Clinic representatives may also have knowledge regarding CDC and OSHA guidelines, as well as infectious disease prevention. Clinic representatives may also have knowledge regarding

patient care and treatment and professional obligations of medical practitioners. Please also see Plaintiffs' expert disclosures.

5. Pat Appleby, c/o Garlington, Lohn & Robinson, PLLP. Ms. Appleby has knowledge regarding her medical conditions, treatment, vaccination/immunity status, and medical advice she has received. Ms. Appleby has knowledge regarding the types of activities she can safely engage in, and her tactics for preventing contracting communicable diseases.

6. Mark Carpenter, c/o Garlington, Lohn & Robinson, PLLP. Mr. Carpenter has knowledge regarding his medical conditions, treatment, vaccination/immunity status, and medical advice he has received. Mr. Carpenter has knowledge regarding the types of activities he can safely engage in, and his tactics for preventing contracting communicable diseases.

7. Diana Jo Page, c/o Garlington, Lohn & Robinson, PLLP. Ms. Page has knowledge regarding her medical conditions, treatment, vaccination/immunity status, and medical advice she has received. Ms. Page has knowledge regarding the types of activities she can safely engage in, and her tactics for preventing contracting communicable diseases.

8. Wallace L. Page, c/o Garlington, Lohn & Robinson, PLLP. Mr. Page has knowledge regarding his medical conditions, treatment, vaccination/immunity status, and medical advice he has received. Mr. Page has knowledge regarding the

types of activities he can safely engage in, and his tactics for preventing contracting communicable diseases.

9. Cheyenne Smith, c/o Garlington, Lohn & Robinson, PLLP. Ms. Smith has knowledge regarding her medical conditions, treatment, vaccination/immunity status, and medical advice she has received, as well as knowledge regarding this information for her infant child. Ms. Smith has knowledge regarding the types of activities she, and her infant child, can safely engage in, and her tactics for preventing contracting communicable diseases.

10. Austin Knudsen, Derek Oestreicher and other representatives of the Attorney General's Office and/or Department of Justice, c/o Defendants' counsel. Mr. Knudsen and Derek Oestreicher likely have knowledge regarding enforcement, interpretation and application of Montana Code Annotated § 49-2-312, as well as Defendants' defenses.

11. Laurie Esau, and other representatives of the Department of Labor and Industry, c/o Defendants' counsel. Ms. Esau likely has knowledge regarding enforcement, interpretation and application of Montana Code Annotated § 49-2-312, as well as Defendants' defenses.

12. David King, M.D., 931 Highland Boulevard, Suite 3103, Bozeman, MT 59715, 406-414-5000. Please see Plaintiffs' expert disclosures.

13. David Taylor, M.D., MSc, 931 Highland Boulevard, Suite 3103, Bozeman, MT 59715, 406-414-6109. Please see Plaintiffs' expert disclosures.

14. Bonnie Stephens, M.D., 2827 Fort Missoula Rd., Missoula MT 59804. Please see Plaintiffs' expert disclosures.

15. Marieke Beck, Montana Human Rights Bureau Chief or other representative of the Montana Human Rights Bureau ("HRB"). Ms. Beck or other HRB representative likely has knowledge regarding enforcement, interpretation and application of Montana Code Annotated § 49-2-312. She (or other HRB representative) also has knowledge regarding the HRB's enforcement and application of the ADA, including reasonable accommodations thereunder, as the HRB is the deferral agency for the EEOC. Ms. Beck or other HRB representative likely has additional knowledge regarding Plaintiffs' claims, as well as Defendants' defenses.

16. Vicky Byrd. 20 Old Montana State Highway, Clancy, MT 59634. Ms. Byrd is the CEO of the Montana Nurses Association ("MNA"). Ms. Byrd is believed to have knowledge of MNA, its members, her own experience working in healthcare, personnel policies at Montana healthcare facilities that employ MNA members, the requirements of participation in CMS programs and importance of the same to Montana healthcare facilities, vaccination requirements of CMS-

participating Montana healthcare facilities prior to implementation of House Bill 702, among other information pertinent to the claims made in this case.

17. Carter Anderson, Inspector General of the Montana Department of Public Health and Human Services ("DPHHS"). 2401 Colonial Drive, Helena, MT 59620. It is believed Carter Anderson has information pertinent to enforcement of CMS regulations in Montana as conducted by DPHHS, as well as information as set forth in the Affidavit of Carter Anderson dated March 2, 2022. (Doc. 51-1).

18. Expert witnesses disclosed by Plaintiff-Intervenor and Defendants, as set forth in expert disclosures and expert reports.

19. Witnesses identified in Discovery and Initial Disclosures.

20. Witnesses identified by the Defendants and by Plaintiff-Intervenor.

21. Witnesses necessary for foundation, rebuttal, or impeachment.

This response may be supplemented to the extent additional individuals are identified.

INTERROGATORY NO. 3: Please state in detail the damages or injuries you claim in this case and identify all facts supporting your damages or injuries, all witnesses who will testify in this matter regarding your damages or injuries, and all documents supporting your claimed damages or injuries.

ANSWER: Plaintiffs object to the extent this request seeks information protected by the work product doctrine. Plaintiffs do not seek damages in this

case; Plaintiffs seek declaratory and injunctive relief as set forth in the Second Amended Complaint, based upon the irreparable harms caused by the statute at issue in this case, which include but are not limited to:

1. Conflict with federal law under both the employer and public accommodations obligations under the Americans with Disabilities Act ("ADA"), exposing the institutional Plaintiffs to competing obligations and liabilities under both the ADA and MCA § 49-2-312.

2. Conflict with federal law under OSHA, exposing the institutional Plaintiffs to competing obligations and liabilities under OSHA rules and regulations and MCA § 49-2-312.

3. Conflict with federal law under the Centers for Medicare and Medicaid Services ("CMS") both by disallowing covered facilities from complying with recognized national standards of care for infection disease prevention, and from complying with the specific COVID vaccination requirements, exposing Providence and other covered facilities to losing the ability to participate in the Medicare and Medicaid programs.

4. Exposing hospitals and physician offices to civil and criminal liability for what would otherwise be appropriate and required exercise of infection control prevention protocols, medical ethical standards, applicable standards of care, and

compliance with other legal responsibilities such as but not limited to compliance with other state and federal laws.

5. Placing medical providers, support staff and other staff in healthcare settings at increased risk of harm of contracting communicable diseases in the work place.

6. Depriving offices of private physicians, including Western Montana Clinic and Five Valleys Urology, equal treatment under the law.

7. Depriving hospitals, including Providence Health and Services, equal treatment under the law.

8. Depriving individuals, including the individual Plaintiffs, with compromised immune systems equal treatment under the law.

9. Infringing upon the individual Plaintiffs' constitutional right under the Montana Constitution to seek health in a clean and healthy environment.

10. Placing patients at increased risk of harm of contracting communicable diseases when seeking medical care.

11. Depriving patients access to safe health care in settings that observe all appropriate infection disease prevention protocols, including staff vaccination.

REQUEST FOR PRODUCTION NO. 1: Please produce all documents in your possession, custody, or control identified in your Answer to Interrogatory No. 3.

RESPONSE: Plaintiffs did not identify any documents in response to the foregoing interrogatory. Plaintiffs refer Defendants to the documents produced herein and previously identified through initial disclosures and otherwise. Plaintiffs refer Defendants to Plaintiffs' Expert Disclosures and documents referenced therein and produced therewith. Plaintiffs refer Defendants to the legal authorities referenced in the foregoing interrogatory.

INTERROGATORY NO. 4: Please identify all expert witnesses you intend to call to testify at the trial of this matter and for each expert, please state the subject matter on which the expert is expected to testify, the substance of the facts and opinions to which the expert is expected to testify, and a summary of the grounds for each opinion.

ANSWER: Plaintiffs refer Defendants to Plaintiffs' Expert Witness Disclosure dated July 8, 2022, and incorporate those disclosures and attachments by this reference.

REQUEST FOR PRODUCTION NO. 2: Please produce all documents in your possession, custody, or control related to the expert witnesses identified in your Answer to Interrogatory No. 4.

RESPONSE: Plaintiffs refer Defendants to Plaintiffs' Expert Witness Disclosure dated July 8, 2022, and incorporate those disclosures and attachments by this reference.

REQUEST FOR PRODUCTION NO. 3: Please produce all data, photographs, videos, and other documents or information upon which the opinions of each expert identified in your Answer to Interrogatory No. 4 are based.

RESPONSE: Plaintiffs refer Defendants to Plaintiffs' Expert Witness Disclosure dated July 8, 2022, and incorporate those disclosures and attachments by this reference.

REQUEST FOR PRODUCTION NO. 4: Please produce all documents, including medical information substantiating the claims made in paragraph 23 of the Second Amended Complaint that the individual Plaintiffs suffer "from one or more chronic medical conditions, which require frequent care from physicians. Each of them has a compromised immune system, which makes them especially susceptible to acquiring an infectious disease."

RESPONSE: Plaintiffs object that this request is overly broad, unduly reasonable, and seeks information beyond the scope of allowable discovery, which is neither relevant to the claims at issue nor proportional to the needs of the case.

As to the non-objectionable portion of the request, limiting the request as only to limited and narrow medical information corroborating the base allegations in the complaint pertaining to the individual Plaintiffs' medical conditions, please see PL 1574-1575 which is medical record information identifying Mark

Carpenter's medical condition. Additional documentation has been requested and will be supplemented upon receipt.

For completeness, the following is identification of the pertinent medical conditions of each individual Plaintiff:

1. Mark Carpenter is a kidney transplant patient, which process results in a significantly compromised immune system.

2. Wally Page has been diagnosed with non-Hodgkins lymphoma and multiple myeloma, requiring ongoing chemotherapy treatment.

3. Jo Page is a recent breast cancer survivor, which required chemotherapy, radiation, and surgery. She is Wally's primary caregiver.

4. Cheyenne Smith has been diagnosed with Juvenile Rheumatoid Arthritis since 1996. She also was recently pregnant and recently gave birth to a baby boy.

5. Pat Appleby is a cancer survivor and underwent chemotherapy treatment for granulosa cell ovarian cancer in 2015. She also continues to treat for type 2 diabetes.

REQUEST FOR PRODUCTION NO. 5: Please produce any data, photographs, videos, or other documents stored on the individual Plaintiffs' social media accounts (twitter, Facebook, Instagram, etc.), personal electronic devices, or

other storage devices between March 1, 2020 to the date these discovery requests were served.

RESPONSE: Plaintiffs object that this request is overly broad, unduly burdensome, and seeks information beyond the scope of allowable discovery, which is neither relevant to the claims at issue nor proportional to the needs of the case. The individual Plaintiffs do not seek individual special or general damages from this case.

As to the non-objectionable portion of the request, narrowing the scope of the request to include social media posts and photographs, please see the documents produced herewith.

REQUEST FOR PRODUCTION NO. 6: Please produce any data, photographs, videos, or other documents related to individual Plaintiffs' attendance or participation in small and large gatherings as defined by the Centers for Disease Control and Prevention from March 1, 2020, to the date these discovery requests were served.

RESPONSE: Plaintiffs object that this request is overly broad, not reasonably limited in time, unduly burdensome, and seeks information beyond the scope of allowable discovery, which is not proportional to the needs of the case given the claims at issue. The request is vague insofar as it seeks "data" "or other documents related to" attendance at gatherings. Plaintiffs further object that the

definitions referenced in this response are impermissibly vague to permit a response to a discovery request in this context.

As to the non-objectionable portion of the request, the individual Plaintiffs have reasonably searched for photographs that may depict the Plaintiffs attending certain gatherings. It is impossible to locate every photograph that may depict the Plaintiffs in "small or large gatherings" as defined in the request. Please see the photographs produced herewith.

REQUEST FOR PRODUCTION NO. 7: Please produce any data, photographs, videos, or other documents related to individual Plaintiffs' airline, railway, or other travel from March 1, 2020, to the date these discovery requests were served. This request excludes any automobile or other private transportation in which the individual Plaintiffs were accompanied only by immediate family members.

RESPONSE: Plaintiffs object that this request is overly broad, not reasonably limited in time, unduly burdensome, and seeks information beyond the scope of allowable discovery, which is not proportional to the needs of the case given the claims at issue. Plaintiffs further object that the references to "other travel" and "private transportation" are vague. The request is overly broad and vague to the extent it seeks "data" and "other documents." Plaintiffs further object to the extent the request seeks data, photos, videos or other documents "related to"

certain types of travel – there can be innumerable types of "data" or "documents" that are related to travel and Plaintiffs cannot reasonably locate all potentially responsive documents for these reasons.

As to the non-objectionable portion of this request, Plaintiffs will identify the airline and railway travel from March 1, 2020 to present, and set forth a summary below. If Defendants can identify the types of "data, photographs, videos, or other documents" sought that pertain to these travel occasions, and provide an explanation for why the need for this documentation is proportional to the burden of obtaining it, particularly given Plaintiffs' identification of pertinent airline and railway travel below, Plaintiffs will evaluate the request and may attempt to supplement this response.

- Mark Carpenter flew on an airplane on two occasions to Sacramento, CA, one May 14-19, 2020 and one June 11-16, 2020. He has not had any travel by rail.
- Cheyenne Smith travelled by airplane to Des Moines, Iowa in May of 2021 and to Las Vegas, Nevada in May of 2021.
- Wally and Jo Page have had no airline or railway travel during the requested timeframe.
- Pat Appleby flew on an airplane to Missouri in June 2022.

REQUEST FOR PRODUCTION NO. 8: Please produce any documents related to individual Plaintiffs' requests for reasonable accommodations pursuant to the Montana Human Rights Act and any complaints filed under the Montana Human Rights Act by the individual Plaintiffs against any place of public accommodation. This request seeks responsive documents from the time period beginning January 1, 2018, through the date these discovery requests were served.

RESPONSE: Plaintiffs object to the extent this request seeks reasonable accommodation requests pertaining to anything other than disability discrimination as overly broad and beyond the scope of allowable discovery. Plaintiffs object that to the extent this request seeks information regarding "reasonable accommodations" under MCA § 39-2-312, as that term is vague and has not been defined. As to the non-objectionable portion of the request, documents filed under Montana Human Rights Act are in the possession of the Department of Labor and Industry. While Mark Carpenter has made numerous accommodation requests verbally, Plaintiffs are not in possession of documents responsive to this request. No Plaintiff has filed a complaint before the HRB in the time period requested.

REQUEST FOR PRODUCTION NO. 9: Please produce any documents or information related to reasonable accommodations available under MCA § 49-2-312(3)(b) that the individual Plaintiffs have requested or received.

RESPONSE: Plaintiffs object that this request is overly broad, not limited in time or scope, unduly burdensome, and not proportional to the needs of the case, and further object to the extent the request calls for a legal conclusion as to what types of accommodations are "available" under applicable law. Plaintiffs further object that "reasonable accommodations" available under MCA § 49-2-312(3)(b) is vague and has not been defined, so it is unclear what the request is seeking, particularly because that subsection applies to accommodations provided to employees who do not share vaccination status, not to patients, visitors, or non-employees. As to the non-objectionable portion of the request, Plaintiffs are not in possession of documents responsive to this request.

REQUEST FOR PRODUCTION NO. 10: Please produce any documents related to reasonable accommodations available under the Americans with Disabilities Act requested, received, or denied by the individual Plaintiffs.

RESPONSE: Plaintiffs object that this request is overly broad, not limited in time or scope, unduly burdensome, and not proportional to the needs of the case, and further object to the extent the request calls for a legal conclusion as to what types of accommodations are "available" under applicable law. As to the non-objectionable portion of the request, and limiting the time period of the request to the last 5 years, please see the response to Request for Production No. 8. This response may be supplemented to the extent additional documents are identified.

REQUEST FOR PRODUCTION NO. 11: Please produce any and all documents that support or substantiate Plaintiffs' allegation in Paragraph 35 of the Second Amended Complaint that "MCA 49-2-312 discourages immune-compromised workers, such as the Patients, from accepting potential employment opportunities otherwise available to them at [Offices of Private Physicians] or at Hospitals." This request seeks responsive documents from the time period beginning January 1, 2018, through the date these discovery requests were served.

RESPONSE: Please see Plaintiffs' Expert Disclosures and declarations and the documents attached thereto.

INTERROGATORY NO. 5: In Paragraph 25 of the Second Amended Complaint, Individual Plaintiffs allege that they must "avoid or minimize contact" with "persons who carry or may carry the COVID-19 virus" and must "avoid commercial and professional establishments" that "fail to take steps to minimize the spread of the virus and other common viruses and germs" and must avoid establishments that "employ unvaccinated workers" or are unable to "take necessary measures to protect against preventable diseases." Please describe in detail how you define these quoted phrases from Paragraph 25 of the Second Amended Complaint.

ANSWER: The phrases quoted in the response are defined as to their ordinary meaning. As additional explanation, individuals who are vulnerable due

to age, disability, or health condition are more at risk of contracting and being harmed by vaccine-preventable diseases. These individuals are required to take particular precaution to avoid contracting vaccine-preventable diseases. This applies not only to COVID during the current pandemic, but to all infectious diseases.

For Mark Carpenter specifically, as a kidney transplant patient, he was given a significant amount of guidance prior to the transplant and afterwards regarding the risks of infections because of immunosuppressants. This started back in 2016 when he applied for a kidney transplant and the guidance is ongoing. This included his entire transplant team at Virginia Mason Hospital in Seattle, his primary care physician in Missoula, his nephrologist in Missoula, his infectious disease specialist in Missoula, and the Missoula County Health Department where he received a large number of vaccinations strongly recommended by his various medical providers. People on immunosuppressants are given guidance to the extent of avoiding things like salad bars due to the risk of infection for diseases like Hepatitis B. In order to protect himself during the pandemic, he did extensive research on his own following clinical studies at John Hopkins and elsewhere. This is how he discovered that the vaccines might not produce antibodies for him and what levels of antibodies are expected to provide protection. For these reasons, he has not attended large gatherings (conferences, trade shows, sporting

events, festivals, concerts, or weddings) since the pandemic began. Since March 2020, he has lived at his remote cabin on Salmon Lake and kept his interactions to a very small group of friends and family who were fully vaccinated and exercised caution.

For Wally Page, he avoided seeing people and establishments who disregarded masking and vaccination recommended by health care professionals. Jo Page limited places she visited to healthcare establishments, where providers masked and followed distancing protocols.

Cheyenne Smith was pregnant during the pandemic and exercised caution when in public. Pat Appleby also exercised caution when leaving the house or going to the grocery store.

REQUEST FOR PRODUCTION NO. 12: Please produce all documents in your possession, custody, or control identified in your Answer to Interrogatory No. 5.

RESPONSE: Plaintiffs did not identify specific documents in the answer to Interrogatory No. 5. Mark Carpenter has performed a reasonably diligent search and has determined he did not retain the educational materials noted in the response to Interrogatory No. 5, though those educational materials are likely available online.

REQUEST FOR ADMISSION NO. 1: Please admit that the individual Plaintiffs have visited Providence, or any other health care facility defined by MCA § 50-5-101, since May 7, 2021.

RESPONSE: Admit as to Mark Carpenter. Admit as to Cheyenne Smith. Admit as to Wally and Jo Page. Denied as to Pat Appleby, although she has attended other health care establishments during this time frame.

REQUEST FOR PRODUCTION NO. 13: Please produce all documents in your possession, custody, or control that support or substantiate your Answer to Request for Admission No. 1.

RESPONSE: Plaintiffs object that this request is vague, overly broad, unduly burdensome and not proportional to the needs of the case. It is unclear what documentation is sought to substantiate the response to the previous request for admission.

REQUEST FOR ADMISSION NO. 2: Please admit that WMC, FVU, PH&S, and other health care providers employ individuals unvaccinated for COVID-19 and other infectious diseases.

RESPONSE: Plaintiffs object to the reference to "other infectious diseases" as vague, overly broad and not sufficiently defined. As to the non-objectionable portion of this request, Plaintiffs admit Providence employs individuals unvaccinated against COVID-19 but who have an approved exemption

pursuant to the CMS COVID vaccine requirements; Plaintiffs admit that Five Valleys and Clinic employ individuals who were, at one point in time, known not to be vaccinated against COVID-19 when such vaccines were available.

REQUEST FOR PRODUCTION NO. 14: Please produce any and all documents in your possession, custody, or control relating to your decision to initiate this action, including board minutes, membership polling, membership and employee communications received and sent, press releases, or communications to other entities or individuals soliciting joining the action—even if those entities or individuals declined to join.

RESPONSE: Plaintiffs object that this request seeks information protected by the attorney client privilege and work product doctrines, and further seeks information beyond the scope of allowable discovery. Please see the privilege log provided herewith.

INTERROGATORY No. 6: Please provide to total number of MMA members for the years 2018, 2019, 2020, 2021, and 2022.

ANSWER: MMA's membership for the noted years is as follows:

2018	2019	2020	2021	2022
1402	1472	1445	1469	1466

REQUEST FOR PRODUCTION NO. 15: Please produce any and all documents in your possession, custody, or control related to how you comply with

29 U.S.C. § 654(a)(1), including but not limited to relevant facility plans, operational plans, employment requirements, and employee assignments.

RESPONSE: Plaintiffs objects that this request is overly broad, not limited in time or scope, unduly burdensome, and not proportionate to the needs of the case. Plaintiffs further object to the extent this request seeks information from the individual Plaintiffs or the MMA. Plaintiffs object to the extent this request calls for a legal conclusion, and to the extent it seeks documents protected by the attorney-client privilege and/or work product doctrine. As to the non-objectionable portion of the request, and limiting the request as seeking OSHA policies pertaining to infectious disease prevention from January 1, 2020 to present, please see the documents produced herewith.

REQUEST FOR PRODUCTION NO. 16: Please produce any and all documents in your possession, custody, or control related to how you comply with 29 C.F.R. § 1910.502, including but not limited to relevant facility plans, operational plans, employment requirements, and employment assignments.

RESPONSE: Plaintiffs objects that this request is overly broad, unduly burdensome, and not proportionate to the needs of the case. Plaintiffs further object to the extent this request seeks information from the individual Plaintiffs or the MMA. Plaintiffs object to the extent this request calls for a legal conclusion, and to the extent it seeks documents protected by the attorney-client privilege

and/or work product doctrine. As to the non-objectionable portion of the request, and limiting the request as seeking policies pertaining to 29 C.F.R. § 1910.502 from January 1, 2020 to present, please see the policy documents of the Clinic, Five Valleys and Providence produced herewith.

REQUEST FOR PRODUCTION NO. 17: Please produce any and all documents in your possession, custody, or control related to how you comply with 42 C.F.R. § 482.41, including but not limited to facility plans, operational plans, employment requirements, and employee assignments.

RESPONSE: Plaintiffs objects that this request is overly broad, not limited in time or scope, unduly burdensome, and not proportionate to the needs of the case. Plaintiffs further object to the extent this request seeks information from the individual Plaintiffs, the MMA, Clinic, and Five Valleys. Plaintiffs object to the extent this request calls for a legal conclusion, and to the extent it seeks documents protected by the attorney-client privilege and/or work product doctrine. As to the non-objectionable portion of the request, and limiting the request as seeking policies only from Providence pertaining to infectious disease prevention from January 1, 2020 to present, please see the Providence policy documents produced herewith.

REQUEST FOR PRODUCTION NO. 18: Please produce any and all documents in your possession, custody, or control related to how you comply with

42 C.F.R. § 482.42, including but not limited to facility plans, operational plans, employment requirements, and employee assignments.

RESPONSE: Plaintiffs objects that this request is overly broad, not limited in time or scope, unduly burdensome, and not proportionate to the needs of the case. Plaintiffs further object to the extent this request seeks information from the individual Plaintiffs, MMA, Clinic, and Five Valleys. Plaintiffs object to the extent this request calls for a legal conclusion, and to the extent it seeks documents protected by the attorney-client privilege and/or work product doctrine. As to the non-objectionable portion of the request, and limiting the request as seeking policies only from Providence pertaining to infectious disease prevention from January 1, 2020 to present, please see the Providence policy documents produced herewith.

REQUEST FOR PRODUCTION NO. 19: Please produce any and all documents in your possession, custody, or control related to how you comply with 42 C.F.R. § 482.42(g), including but not limited to facility plans, operational plans, employment requirements, and employee assignments.

RESPONSE: Plaintiffs objects that this request is overly broad, not limited in time or scope, unduly burdensome, and not proportionate to the needs of the case. Plaintiffs further object to the extent this request seeks information from the individual Plaintiffs, MMA, Clinic, and Five Valleys. Plaintiffs object to the

extent this request calls for a legal conclusion, and to the extent it seeks documents protected by the attorney-client privilege and/or work product doctrine. As to the non-objectionable portion of the request, and limiting the request as seeking policies only from Providence pertaining to infectious disease prevention from January 1, 2020 to present, please see the documents produced herewith.

REQUEST FOR PRODUCTION NO. 20: Please produce any and all documents in your possession, custody, or control related to how you comply with MCA § 49-2-312, including but not limited to facility plans, operational plans, employment requirements, and employee assignments.

RESPONSE: Plaintiffs objects that this request is overly broad, not limited in time or scope, unduly burdensome, and not proportionate to the needs of the case. Plaintiffs object to the extent this request seeks information or documents from the individual Plaintiffs or from MMA. Plaintiffs object to the extent this request calls for a legal conclusion, and to the extent it seeks documents protected by the attorney-client privilege and/or work product doctrine. As to the non-objectionable portion of the request, please see the policy documents of the Clinic, Five Valleys and Providence produced herewith.

REQUEST FOR PRODUCTION NO. 21: Please produce any and all documents in your possession, custody, or control related to employment policies at Providence, Five Valleys, and Clinic from January 1, 2018, to the present,

including any amendments, recissions, or additions to hiring and employment policies.

RESPONSE: Plaintiffs object that this request is overly broad, unduly burdensome, seeks information beyond the scope of allowable discovery and is not proportionate to the needs of the case. The request is overly broad in that "all policies" "related to" employment policies or practices implicates an innumerable number of different documents pertaining to things such as clocking in and clocking out, breaks, dress codes, paid time off policies, and other employment-related issues that have nothing to do with the claims at issue in this case. As to the non-objectionable portion of the request, and limiting the request as seeking general employee handbooks and policies specifically pertaining to infectious disease control and disability discrimination, please see documents produced herewith.

INTERROGATORY NO. 7: Please provide data explaining the relative health status of patients at PH&S, FVU, and WMC, respectively. Relative health status means the number of patients who are immunocompromised or otherwise disabled (as that term is used in Paragraph 64 of the Second Amended Complaint) compared to the number of patients who are not immunocompromised or otherwise disabled (as that term is used in Paragraph 64 of the Second Amended Complaint), both in terms of number of patients and number of patient visits. Production must

be done for each facility separately. This response asks for monthly data totals from January 2020 through June 2022. Defendants provide the following template to the extent Plaintiffs find it helpful in answering this Interrogatory:

ANSWER: Plaintiffs object that this interrogatory is three separate interrogatories and will be counted as such against Defendants' total number of allowable interrogatories. Plaintiffs object to and are ignoring the suggested template provided in the request as not permitted under the Rules.

Plaintiffs further object that this request is overly broad, unduly burdensome, seeks information beyond the scope of allowable discovery, and is not proportional to the needs of the case. Plaintiffs object that "relative health status" is vague and ambiguous. Plaintiffs further object to the extent it seeks protected health information of individual patients.

Providence sees approximately 138 inpatients patients per day at the St. Patrick Hospital location alone, and has had 149,207 outpatient visits and 164,795 physician office and ER visits from January 1, 2022 through June 30, 2022. St. Joseph Medical Center sees an average of 6 inpatients per day, and has had 28,214 outpatient visits and 20,881 physician office and ER visits from January 1, 2022 through June 30, 2022. Patient totals for 2021 and 2020 are approximately double these figures.

Five Valleys sees approximately 1,400 patients on average per month. The Clinic sees approximately 110 patients on average per day, including additional patients of the lab and infusion center, which constitute an additional 40-80 patients per day.

These entities do not maintain a data set that would permit a response to this request as drafted, and moreover a given patient's medical status changes over time and can change over a given course of treatment.

Accordingly, to respond to this request would require Providence, Five Valleys, and the Clinic to review every patient record for the past two and a half years, and attempt to interpret each patient's chart under a vague and ambiguous standard.

REQUEST FOR PRODUCTION NO. 22: Please produce any and all documents in your possession, custody, or control related to employee or prospective employee requests at PH&S, FVU, or WMC for reasonable accommodations authorized under MCA § 49-2-312, including any documents related to decisions to grant or deny such accommodations.

RESPONSE: Plaintiffs object that this request is not reasonably limited in time or scope and thereby is overly broad, unduly burdensome, and not proportional to the needs of the case. Plaintiffs further object to the extent the request calls for a legal conclusion as to what types of accommodations are

"available" under applicable law. Plaintiffs further object that "reasonable accommodations" available under MCA § 49-2-312(3)(b) is vague and has not been defined, so it is unclear what the request is seeking. Plaintiffs object that this request seeks confidential personnel information of nonparties.

Five Valleys and the Clinic further object that the "reasonable accommodations" provision in MCA § 49-2-312(3)(b) is not applicable to offices of private physicians.

Moreover, Providence further objects that their records related to accomodation requests are not segregated or organized by type of accommodation request. Providence states that many accommodation requests are made and fulfilled without documentation. Providence has had a total of 193 documented accommodation requests from employees for calendar years 2020, 2021, and 2022.

REQUEST FOR PRODUCTION NO. 23: Please produce any and all documents in your possession, custody, or control related to employee or prospective employee requests at PH&S, FVU, or WMC for reasonable accommodations under the Americans with Disabilities Act, since March 1, 2020, including any documents related to decisions to grant or deny such accommodations.

RESPONSE: Plaintiffs object that this request seeks confidential personnel information of nonparties. As to Providence, Plaintiffs further object that this

request is overly broad and unduly burdensome, and seeks information beyond the scope of allowable discovery, as ADA accommodation requests implicate a host of issues and subject matter that has nothing to do with the claims at issue in this lawsuit. Providence has had a total of 193 documented accommodation requests from employees for calendar years 2020, 2021, and 2022.

For the Clinic, the Clinic received 8 requests for exemption from the COVID vaccine mandate (produced herewith) preemptively prior to implementation deadline, which became moot when the OSHA vaccine mandate was enjoined. WMC also handled a request for accommodation related to a hearing impairment, but did so without a formal paperwork process. Five Valleys is not in possession of documents responsive to this request.

REQUEST FOR PRODUCTION NO. 24: Please produce any and all documents in your possession, custody, or control related to requests by patients, visitors, or other non-employees at PH&S, FVU, or WMC for reasonable accommodations authorized under MCA § 49-2-312, including any documents related to decisions to grant or deny such accommodations.

RESPONSE: Plaintiffs object that this request is overly broad, unduly burdensome, and not proportional to the needs of the case. Plaintiffs further object to the extent the request calls for a legal conclusion as to what types of accommodations are "available" under applicable law. Plaintiffs further object that

"reasonable accommodations" available under MCA § 49-2-312(3)(b) is vague and has not been defined, so it is unclear what the request is seeking, particularly because that subsection applies to accommodations provided to employees who do not share vaccination status, not to patients, visitors, or non-employees. Plaintiffs further object to the extent this request seeks protected health information of patients, and further states that accommodation requests of any type requested by a patient are documented in the patient's medical record and not separately maintained.

Five Valleys and the Clinic further object that the "reasonable accommodations" provision in MCA § 49-2-312(3)(b) is not applicable to offices of private physicians.

Moreover, Providence further objects based upon the fact that written accommodation requests from non-employees are documented through the general incident report process, and that such reports are not segregated or organized in a manner that would be searchable by type of incident. Providence states that many accommodation requests are made and fulfilled without documentation.

REQUEST FOR PRODUCTION NO. 25: Please produce any and all documents in your possession, custody, or control related to requests by patients, visitors, or other non-employees at PH&S, FVU, or WMC for reasonable accommodations authorized under the Americans with Disabilities Act, since

March 1, 2020, including any documents related to decisions to grant or deny such accommodations.

RESPONSE: As to Providence, Plaintiffs object that this request is overly broad and unduly burdensome, and seeks information beyond the scope of allowable discovery, as ADA accommodation requests implicate a host of issues and subject matter that has nothing to do with the claims at issue in this lawsuit

Plaintiffs further object to the extent the request calls for a legal conclusion as to what types of accommodations are "authorized" under applicable law. Plaintiffs further object to the extent this request seeks protected health information of patients, and further states that accommodation requests of any type requested by a patient are documented in the patient's medical record and not separately maintained.

Moreover, Providence further objects based upon the fact that written accommodation requests from non-employees are documented through the general incident report process, and that such reports are not segregated or organized in a manner that would be searchable by type of incident. Providence states that many accommodation requests are made and fulfilled without documentation.

As to the non-objectionable portion of the request, Five Valleys and the Clinic are not aware of requests for accomodation by non-patients and non-employees.

REQUEST FOR PRODUCTION NO. 26: Please produce any and all documents in your possession, custody, or control related to complaints filed against PH&S, FVU, or WMC under the Americans with Disabilities Act, since March 1, 2020.

RESPONSE: Plaintiffs are not currently in possession of documents responsive to this request.

REQUEST FOR PRODUCTION NO. 27: Please produce any and all documents in your possession, custody, or control related to complaints filed under MCA § 49-2-312.

RESPONSE: Plaintiffs object to the extent "related to" implicates documents protected by the attorney-client privilege and work product doctrine. As to the non-objectionable portion of the request, please see the documents produced herewith related to complaints filed against Providence pursuant to MCA § 49-2-312.

REQUEST FOR PRODUCTION NO. 28: Please produce any and all documents in your possession, custody, or control related to notices of non-compliance with MCA § 49-2-312.

RESPONSE: Plaintiffs object that "notices of non-compliance" is vague. If this term is clarified Plaintiffs will re-evaluate this response. As to the non-objectionable portion of the request, construing "notices of non-compliance" to

mean complaints filed under MCA § 49-2-312, please see the response to Request for Production No. 27 and documents produced thereto.

REQUEST FOR PRODUCTION NO. 29: Please produce any and all documents in your possession, custody, or control related to violations of the Americans with Disabilities Act since January 1, 2018.

RESPONSE: Plaintiffs object that the request is vague insofar as what is meant by documents "related to violations" of the ADA. Construing the request as seeking documents pertaining to formal adverse findings of violations of the ADA, Plaintiffs are not currently in possession of documents responsive to the request.

REQUEST FOR PRODUCTION NO. 30: Please produce any and all documents in your possession, custody, or control related to violations of the Occupational Safety and Health Act since January 1, 2018.

RESPONSE: Plaintiffs object that the request is vague insofar as what is meant by documents "related to violations" of OSHA, and further object that the request is overbroad to the extent OSHA regulates aspects of the workplace wholly unrelated to the claims at issue in this case. Construing the request as seeking documents pertaining to formal adverse findings of violations of OSHA related to infection control or disease prevention, Plaintiffs are not currently in possession of documents responsive to the request.

REQUEST FOR PRODUCTION NO. 31: Please produce any and all documents in your possession, custody, or control related to notices of non-compliance with any state or federal rules under the Centers for Medicare & Medicaid Conditions of Participation (referenced in Paragraph 79 of the Second Amended Complaint) since January 1, 2018.

RESPONSE: Plaintiffs object that the request is overly broad and unduly burdensome in that there are many different rules under CMS Conditions of Participation for various types of entities and providers. Plaintiffs object that the request is vague insofar as what is meant by documents related to "notices of non-compliance" of CMS Conditions of Participation, and further object that the request is overbroad to the extent the CMS Conditions of Participation implicate issues and matters wholly unrelated to the claims at issue in this case. Plaintiffs object that the CMS Conditions of Participation do not apply directly to the Clinic or Five Valleys, though numerous requirements for individual physician participation in Medicare and Medicaid would apply to individual physicians.

As to the non-objectionable portion of the request, construing the request as seeking documents pertaining to formal adverse findings of violations of the CMS Conditions of Participation, or other formal "notices of non-compliance" related to infection control or disease prevention and as to Providence only, Plaintiffs are not currently in possession of documents responsive to the request.

INTERROGATORY NO. 8: Pertinent to your allegations in Paragraph 83 of the Second Amended Complaint, please provide the amount of Providence's total annual revenue, Providence's total annual operating expenses, Providence's annual Medicare reimbursements, and Providence's annual Medicaid reimbursements for each year beginning in 2018.

ANSWER: Please see below.

Providence Health and Services - Montana
dba St. Patrick Hospital/Providence Medical Group

	2018	2019	2020	2021
Patient Revenue	395,698,813	411,548,125	387,672,108	433,535,229
Non-patient Revenue	19,279,599	20,031,660	30,919,393	31,735,465
Expenses	393,864,767	399,330,514	401,408,424	438,398,122
Revenue				
Medicare %	40.89%	42.08%	41.58%	42.81%
Medicaid %	12.70%	13.26%	14.93%	14.64%

Providence St. Joseph Medical Center

	2018	2019	2020	2021
Patient Revenue	37,101,427	38,733,775	39,385,849	41,387,279
	3,524,359	3,779,555	1,488,109	3,507,333

Non-patient Revenue				
Expenses	40,683,533	46,896,746	46,128,973	48,400,009
Revenue				
Medicare %	36.52%	37.07%	35.81%	37.40%
Medicaid %	34.29%	34.36%	36.41%	35.14%

REQUEST FOR PRODUCTION NO. 32: Please produce all documents supporting or substantiating the answer to Interrogatory 8.

RESPONSE: Plaintiffs object that this request is overly broad and unduly burdensome, as it implicates an innumerable number of documents that reflect revenues, expenses, and percentages of Medicare and Medicaid reimbursement. As to the non-objectionable portion of the request, see the IRS Form 990 for St. Patrick Hospital and IRS Form 990 for St. Joseph Medical Center, produced herewith (PL 338-541).

REQUEST FOR ADMISSION NO. 3: Please admit the allegations in paragraphs 79 to 92 apply only to PH&S and not to other named Plaintiffs.

RESPONSE: Denied as written. To the extent reference is made to the Second Amended Complaint, Plaintiffs state that the allegations set forth in paragraphs 79-83 relate to all facilities required to satisfy the CMS Conditions of Participation for participation in the Medicare and Medicaid programs. Paragraphs

84-92 constitute Plaintiffs' Eighth Claim for Violation of CMS Regulations, and make reference to all applicable CMS Regulations. These allegations and this claim impacts all physicians (including but not limited to those MMA members and physicians employed or contracted at Five Valleys and Clinic) who are on the medical staffs of facilities subject to the CMS Conditions of Participation. Moreover, Five Valleys (while not directly subject to the CMS regulations at issue) is part owner in an ambulatory surgery center, to which the CMS Conditions of Participation apply.

REQUEST FOR PRODUCTION NO. 33: Please produce any and all documents in your possession, custody, or control, including communications to or from employees or members, plans, or policies related to vaccination requirements or recommendations for any disease since January 1, 2018.

RESPONSE: Plaintiffs object to the extent this request seeks information from the individual Plaintiffs or the MMA. Plaintiffs object that this request is overly broad and unduly burdensome as to every communication made to any employee, and further object that the request is vague as to what is meant by "members" and "plans." Providence currently has 2,838 employee positions in the Montana service area, Five Valleys has 40 employees, and the Clinic has 190 employees. Plaintiffs cannot possibly know or locate every communication with every person on this topic. To the extent this topic is limited to the last three years

and relates to official statements and bulletins made on behalf of Providence, Five Valleys, and the Clinic to employees and policies related to vaccination requirements and recommendation, please see the documents produced herewith.

REQUEST FOR PRODUCTION NO. 34: Please produce any and all documents in your possession, custody, or control, including communications to or from employees or members, plans, or policies related to minimizing the spread (as that term is used in Paragraph 25 of the Second Amended Complaint) of pathogens since January 1, 2018.

RESPONSE: Plaintiffs object to the extent this request seeks information from the individual Plaintiffs or the MMA. Plaintiffs object that this request is overly broad and unduly burdensome as to every communication made to any employee, and further object that the request is vague as to what is meant by "members" and "plans." Providence currently has 2,838 employee positions in the Montana service area, Five Valleys has 40 employees, and the Clinic has 190 employees. Plaintiffs cannot possibly know or locate every communication with every person on this topic. To the extent this topic is limited to the last three years and relates to official statements and bulletins made on behalf of Providence, Five Valleys, and the Clinic to employees and policies related to vaccination requirements and recommendation, please see the email communications and policies pertaining to Providence, Five Valleys and the Clinic produced herewith.

REQUEST FOR PRODUCTION NO. 35: Please produce any and all documents in your possession, custody, or control related to applications or qualifications for participation in Medicare and Medicaid submitted to CMS or the Montana Department of Public Health and Human Services since January 1, 2018.

RESPONSE: Plaintiffs object to the extent this request applies to the individual Plaintiffs or the MMA. Plaintiffs object that the request is vague as "applications or qualifications" in Medicare and Medicaid and overly broad and unduly burdensome in that there are many different rules and qualifications under CMS Conditions of Participation for various types of entities and providers, implicating issues and matters wholly unrelated to the claims at issue in this case. Plaintiffs object that the CMS Conditions of Participation do not apply directly to the Clinic or Five Valleys, though numerous requirements for individual physician participation in Medicare and Medicaid would apply to individual physicians.

As to the non-objectionable portion of the request, construing the request as seeking documents pertaining survey audits for CMS compliance and for Providence only, please see the Joint Commission audit produced herewith (PL 236-282).

REQUEST FOR ADMISSION NO. 4: Please admit that Plaintiffs FVU and WMC chose and continue to choose not to apply and operate as licensed "health care facilit[ies]" as defined in MCA § 50-5-101(26).

RESPONSE: Plaintiffs object to this request as argumentative, assumes facts not in evidence, and not an appropriate request under Rule 36. Plaintiffs state that Five Valleys and Clinic are not required to apply for separate licensure as a health care facility under Montana's licensure laws to operate a physician practice, nor is there a type of health care facility that is necessarily appropriate for the operation of a physician clinic.

INTERROGATORY NO. 9: Please explain in detail the current infectious disease prevention protocols (as that term is used in Paragraph 18 of the Second Amended Complaint) in operation by PH&S, FVU, and WMC.

ANSWER: Plaintiffs object that this request is overly broad, unduly burdensome, as infectious disease prevention protocols are numerous and can take numerous forms. As to the non-objectionable portion of the request, please see the infection control policies of the institutional Plaintiffs produced herewith.

REQUEST FOR PRODUCTION NO. 36: Please produce any and all documents in your possession, custody, or control identified in your Answer to Interrogatory No. 9.

RESPONSE: Please see the response to Interrogatory No. 9 and documents produced herewith.

INTERROGATORY NO. 10: Please explain in detail the infectious disease prevention protocols (as that term is used in Paragraph 18 of the Second

Amended Complaint) in operation at facilities like PH&S, FVU, and WMC between January 1, 2019, and March 1, 2020.

ANSWER: Plaintiffs object that this request is overly broad and unduly burdensome, as infectious disease prevention protocols are numerous and can take numerous forms. As to the non-objectionable portion of the request, limited to these entities' policies for the applicable time period, please see the documents produced herewith.

REQUEST FOR PRODUCTION NO. 37: Please produce any and all documents in your possession, custody, or control identified in your Answer to Interrogatory No. 10.

RESPONSE: Please see the response to Interrogatory No. 10 and documents produced herewith.

INTERROGATORY NO. 11: Please explain in detail every instance, from January 1, 2018, though the date these discovery requests are served, in which any Plaintiff declined to refer a patient to another provider or facility due to that other provider's or facility's staff vaccination status.

ANSWER: Plaintiffs object that this request is overly broad and unduly burdensome, and not proportional to the needs of the case. Providence has approximately 178 physician providers and 107 midlevel providers in the Montana service area, Five Valleys has 5 physician providers and 2 midlevel providers, and

the Clinic has 31 physicians and numerous midlevel providers. This request implicates individual medical decisions by individual medical providers. Moreover, Providence sees approximately 138 inpatients patients per day at the St. Patrick Hospital location alone, and has had 149,207 outpatient visits and 164,795 physician office and ER visits from January 1, 2022 through June 30, 2022. St. Joseph Medical Center sees an average of 6 inpatients per day, and has had 28,214 outpatient visits and 20,881 physician office and ER visits from January 1, 2022 through June 30, 2022. Patient totals for 2021 and 2020 are approximately double these figures. Five Valleys sees approximately 1,400 patients on average per month. The Clinic sees approximately 110 patients on average per day, including additional patients of the lab and infusion center, which constitute an additional 40-80 patients per day.

Plaintiffs further object to the extent this request seeks protected health information of patients.

REQUEST FOR PRODUCTION NO. 38: Please produce any and all documents in your possession, custody, or control identified in your Answer to Interrogatory No. 11.

RESPONSE: Plaintiffs incorporate the response and objections to Interrogatory No. 11.

REQUEST FOR PRODUCTION NO. 39: Please produce any and all documents in your possession, custody, or control related to communications from you to members of the Montana Legislature, Montana Department of Health and Human Services, or Montana Governor's Office related to passage and implementation of House Bill 702.

RESPONSE: Plaintiffs object that this request is overly broad and unduly burdensome. As to the non-objectionable portion of the request, limiting the request as seeking official communications on behalf of the respective entities, please see MMA's letter to Governor Gianforte produced herewith. PL 1443-1445.

REQUEST FOR PRODUCTION NO. 40: Please produce any and all documents in your possession, custody, or control related to support or opposition to HB 702, including internal decisions to support or oppose HB 702, as well as any related employee or member communications.

RESPONSE: Plaintiffs object that this requests is overly broad, unduly burdensome, seeks information beyond the scope of allowable discovery and is not proportional to the needs of the case. Plaintiffs further object to the extent this request seeks information protected by the attorney client privilege and work product doctrine. As to the non-objectionable portion of the request, the individual plaintiffs, Providence, Five Valleys, and the Clinic are not in possession of

nonprivileged documents responsive to this request. Please see enclosed privilege log. As to the non-objectionable portion of the request related to the MMA, please see the response to Request for Production No. 39, documents produced thereto as well as the documents produced herewith.

REQUEST FOR PRODUCTION NO. 41: Please produce all documents in your possession, custody, or control related to your implementation of HB 702, including all internal decision-making communications, as well as any related employee or member communications.

RESPONSE: Plaintiffs object to the request as vague as to what is meant by "implementation of" HB 702. Individuals and individual facilities do not "implement" a law, much less a bill. To the extent this request seeks policies and official communications from Providence, Five Valleys and the Clinic implemented after HB 702 was signed into law, please see such documents produced herewith.

REQUEST FOR PRODUCTION NO. 42: Please produce any and all documents in your possession, custody, or control related to survey deficiencies, as used in 42 C.F.R. § 488, et seq., issued by any governmental entity or contractor to you pursuant to your conditions of participation in Medicare and Medicaid since January 1, 2018.

RESPONSE: Plaintiffs object to the extent this request applies to the

individual Plaintiffs, MMA, the Clinic or Five Valleys. Plaintiffs object that the request is vague as to what is meant by "deficiencies," and is overly broad and unduly burdensome to the extent the CMS Conditions of Participation implicate issues and matters wholly unrelated to the claims at issue in this case. Plaintiffs object that the CMS Conditions of Participation do not apply directly to the Clinic or Five Valleys, though numerous requirements for individual physician participation in Medicare and Medicaid would apply to individual physicians.

As to the non-objectionable portion of the request, construing the request as seeking documents pertaining to formal survey deficiencies as to Providence only, Plaintiffs are not currently in possession of documents responsive to the request. For completeness, please see the Joint Commission survey for Providence produced herewith (PL 236-282).

REQUEST FOR ADMISSION NO. 5: Please admit that the CMS, COVID-19 vaccine mandate, as contained in Interim Final Rule, Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555 (Nov. 5, 2021), does not mandate covered facilities to require COVID-19 vaccine booster doses.

RESPONSE: Plaintiffs admit that the current CMS COVID-19 vaccine mandate does not currently mandate covered facilities to require COVID-19 vaccine "booster" doses, as that term is used and defined in the Interim Final Rule

and regulations, but does require covered facilities to have a process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC. There are other CMS Conditions of Participation that require covered facilities to implement appropriate infection disease prevention protocols.

REQUEST FOR ADMISSION NO. 6: Please admit that prior to the U.S. Department of Labor's COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021), the Occupational Safety and Health Act had never previously been used to mandate vaccination for any disease.

RESPONSE: Plaintiffs admit that prior to the OSHA emergency temporary standard noted in the request, OSHA had not issued a regulation, rule or standard mandating vaccination for a disease. To the extent the request seeks information regarding mandates from a source other than OSHA, the request is overly broad and unduly burdensome and Plaintiffs could not admit or deny the same.

REQUEST FOR ADMISSION NO. 7: Please admit that CMS stated in the Interim Final Rule, Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555 (Nov. 5, 2021), "we have not, until now, required any health care staff vaccinations" as condition of participation in Medicare or Medicaid.

RESPONSE: Plaintiffs object that this request is argumentative and omits critical context of the quoted material. Plaintiffs state that the entire quote partially identified in the response is as follows:

> While we have not, until now, required any health care staff vaccinations, we have established, maintained, and regularly updated extensive health and safety requirements (CfCs, CoPs, requirements, etc.) for Medicare- and Medicaid- certified providers and suppliers.

86 Fed. Reg. 61568.

REQUEST FOR ADMISSION NO. 8: Please admit that the Montana Department of Health and Human Services has never required staff vaccination as a condition of participation in Medicaid.

RESPONSE: Plaintiffs object that this request is overly broad, unduly burdensome, argumentative, assumes inaccurate facts, and seeks information not in the possession of Plaintiffs. Plaintiffs are unable to answer this request as Montana DPHHS is not responsible for establishing the conditions of participation for Medicaid.

INTERROGATORY NO. 12: Please explain in detail what steps, if any, individual Plaintiffs took prior to May 7, 2021 to assess the vaccination or immunity status of employees or personnel at any commercial or professional establishment before entering it.

ANSWER: Plaintiffs object that this request is overly broad, unduly

burdensome and not limited to a discreet timeframe. As to the non-objectionable portion of the request, in general, prior to the COVID pandemic, the individual plaintiffs did not believe vaccination was an issue, due to the fact that vaccinations were a common requirement for the military, public schools, and daycares. Individual plaintiffs were unaware of the magnitude of the anti-vaccination movement prior to the pandemic. Mark Carpenter, for example, assumed most individuals were vaccinated, as vaccination status had never previously been a political issue and vaccinations were a common requirement of people proceeding through the public school system. In healthcare settings, Mark Carpenter assumed vaccination was a requirement of employment to protect patients, given that vaccinations were mandated for public schools and daycares.

REQUEST FOR PRODUCTION NO. 43: Please produce all documents in your possession, custody, or control identified in your Answer to Interrogatory No. 12.

RESPONSE: Plaintiffs did not identify documents in response to Interrogatory No. 12.

INTERROGATORY NO. 13: Please describe in detail all the studies, data, statistics, findings, or other information regarding COVID-19 vaccination's relationship to COVID-19 transmission that you believe support Plaintiffs' claims.

ANSWER: Plaintiffs refer Defendants to Plaintiffs' expert disclosures and the studies and other supporting material referenced therein. Plaintiffs anticipate relying on studies and data issued by the CDC and other agencies. Plaintiffs state that the data and studies supporting the efficacy of the COVID vaccines is evolving.

REQUEST FOR PRODUCTION NO. 44: Please produce all documents in your possession, custody, or control identified in your Answer to Interrogatory No. 13.

RESPONSE: Please see Plaintiffs' expert disclosures and the supporting documents and information produced therewith and referenced therein.

INTERROGATORY NO. 14: Please describe in detail all the studies, data, statistics, findings, or other information regarding the relationship between vaccination for diseases other than COVID-19 and the transmission of those other diseases that you believe support Plaintiffs' claims.

ANSWER: Plaintiffs refer Defendants to Plaintiffs' expert disclosures and the studies and other supporting material referenced therein.

REQUEST FOR PRODUCTION NO. 45: Please produce all documents in your possession, custody, or control identified in your Answer to Interrogatory No. 14.

RESPONSE: Please see Plaintiffs' expert disclosures and the supporting

documents and information produced therewith and referenced therein.

DATED this 29th day of July, 2022.

Attorneys for Plaintiffs:

GARLINGTON, LOHN & ROBINSON, PLLP

By _____
Justin K. Cole

CERTIFICATE OF SERVICE

I hereby certify that on July 29, 2022, a copy of the foregoing document was served on the following persons by the following means:

_____	Hand Delivery
1-3	Mail
_____	Overnight Delivery Service
_____	Fax (include fax number in address)
1-3	E-Mail (include email in address)

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Exhibit 10

GARLINGTON | LOHN | ROBINSON
MONTANA'S ATTORNEYS SINCE 1870

August 12, 2022

Sent Via Email Only
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RE: Montana Medical Association et al. v. Austin Knudsen et al.

Dear Christian:

This letter is in response to your 19-page meet and confer letter which was sent to us at 5:28 p.m. on August 10, 2022. We will respond to each issue you raised in your letter, as follows. As always, our goal is to work with you to attempt to resolve these issues.

As to your allegations of timing of production of documents, the discovery requests propounded on the Plaintiffs were extraordinarily broad. Defendants did not serve discovery until June 29, 2022, despite the fact the lawsuit was initiated in September 2021. Defendants served 45 requests for production and 13 interrogatories. The requests for production are improperly broad and unduly burdensome on Plaintiffs, particularly in a case in which both parties acknowledge and agree that the issues to be litigated are primarily legal – not factual. Standing has already been established in this case, and numerous of the requests made in the discovery responses and again in your meet and confer letter appear designed to require Plaintiffs to factually establish standing.

Despite the breadth and unduly onerous nature of the requests, Plaintiffs have endeavored to provide full and complete responses to the discovery. Typically, given the volume and scope of the requests and documents implicated by the requests, Plaintiffs would have sought one or more extensions of time. Given depositions were commencing just two days after Plaintiffs' deadline under the rules due to when Defendants served the requests, Plaintiffs timely responded to Defendants' discovery requests on July 29, 2022, to the extent they were able. Plaintiffs responded to all requests and provided 1,447 documents.

Plaintiffs continued to search for responsive documents, and pursuant to FRCP 26(e), timely supplemented responses one week later (37 days after the requests were served) and provided

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additional documents. Plaintiffs again supplemented three days later and provided additional documents. Plaintiffs provided the additional documents as quickly as counsel was able to obtain and review the documents, and we worked very hard to get as many documents to you as we could prior to additional depositions. Plaintiffs again supplemented three days after that (43 days after the discovery requests were served). All of these productions have been unprompted, within the discovery deadline and have occurred as soon as possible after the documents were located and identified.

We appreciate the challenges presented with the tight discovery deadline and numerous depositions, which have been compounded by the incredibly broad discovery requests propounded by Defendants. It does not appear that any of the documents you cite in your letter as being produced in supplemental discovery were utilized as deposition exhibits, despite your acknowledgement that you were reviewing them prior to the depositions. In fact, some of the documents were identified as potential exhibits, but Defendants ultimately chose not to utilize them in the depositions. Nonetheless, we certainly understand the document production schedule in this case has been tight given when Defendants' initial requests were served. We can assure you we do not engage in gamesmanship – that is not how we practice law. We will continue to work with you in good faith as we press forward in this litigation and conclude discovery.

Request for Production No. 4

We are working with the individual Plaintiffs to obtain narrow medical record documentation confirming their medical diagnoses. Most individuals do not have direct access to these records and these need to be obtained from their medical providers. We supplemented discovery and provided you with medical records confirming the diagnoses for Wally and Jo Page. We do dispute your characterization of the extent to which these individual Plaintiffs have placed their medical condition at issue. These individuals have alleged their medical conditions generally, and in our discovery we provided you with the specific medical conditions of each Plaintiff. But participation in this lawsuit has not put all of Plaintiffs' medical records or medical conditions at issue. They do not seek damages, and this is not a personal injury case. If there is specific information, other than their diagnoses, that you believe you need, please let us know and we consider such requests. To expedite and avoid the need to have each of these individuals deposed, we are happy to provide you with declarations attesting to the medical diagnoses as set forth in the discovery. Please let us know if this will suffice.

Request for Production No. 5, 6, and 7

These requests are overly broad, and their overbreadth is apparent by the text of the requests themselves. The request seeks "any data", "any photographs," "and videos," and "any…other

documents." RFP 5 asks for these categories of data stored either on social media accounts, personal electronic devices, or "other storage devices" for over a two year period. It would be impossible to provide all "data" stored online, on personal electronic devices, or other storage devices. RFP 6 and 7 are not limited to where the data is stored. "Data" or "documents" or "photographs" "related to" attendance at "small or large gatherings" (also not defined, unclear and vague) or Plaintiffs' airline and rail travel is entirely too broad to permit a response. RFP 7 also seeks data and documents "related to…other travel" – excluding only automobile or private transportation in which an individual Plaintiff was accompanied by immediate family members.

The requests are patently overbroad and our objections are supportable. These are not boilerplate objections, but rather tailored to the overbreadth of the request, and in each we explain the manner in which the requests are overly broad or otherwise objectionable, further responding to a limited scope of the request. Again, we struggle to understand how this information is calculated to lead to the discovery of admissible evidence, but nonetheless have worked in good faith to attempt to respond, and will supplement to the extent additional documents are located.

Request for Production No. 8

We reviewed our response to RFP 8 and can confirm the response is accurate. The request did seek legal conclusions to the extent you ask the Plaintiffs to determine whether accommodation requests were made pursuant to or under specifically cited law.

Request for Production No. 9

The objections to this request are warranted and appropriate and we maintain them. Patients do not make reasonable accommodation requests pursuant to the specific cited statute. And, there is no definition of "reasonable accommodation" under the cited statute so it calls for a legal conclusion to which there is no precise legal definition. Nonetheless, this is a non-issue, as Plaintiffs are not in possession of documents responsive to the request.

Request for Production No. 11

We can confirm the response to this request is accurate and all documents that have been identified have been produced with our expert disclosures. Plaintiffs further identify the depositions of Dr. King, Dr. Taylor, Dr. Wilson, and the 30(b)(6) depositions, to the extent they can be deemed responsive.

Interrogatory No. 5

We have reviewed the narrative response to this request, and it contains the response for each Plaintiff. As discussed during our call today, we are revisiting this interrogatory with the individual Plaintiffs and may supplement the response.

Request for Production No. 12

No documents were identified in the response to Interrogatory No. 5, other than the educational materials referenced in relation to Mark Carpenter, which are not in his possession. Thereby, there are no documents to provide in response to this request for production related to that education. The photographs provided by the individual Plaintiffs may also be responsive, but they have been previously provided.

Request for Admission No. 1

Pat Appleby did not attend a "health care facility" as defined by MCA § 50-5-101 but did visit her doctor's office during the requested timeframe, hence the manner in which we articulated the response.

Request for Admission No. 2

This request asked Western Montana Clinic, Five Valleys, and Providence to admit the institutions "employ individuals unvaccinated for COVID-19 and other infectious diseases." We admitted the request as it applied to the COVID-19 vaccine with the detail as noted in the response. As to other "infectious diseases", there are many infectious diseases that have an applicable, even beyond those that have been discussed in this lawsuit, some of which do not have an approved vaccine available. The request is therefore overly broad. But in any event, Plaintiffs did admit the request as it pertained to the COVID-19 vaccine. We are happy to have a further dialogue on this request to see what information Defendants are seeking.

Request for Production No. 15

This request was not time limited, so Plaintiffs put a reasonable time limit on the request. It is overly broad by the text of the request itself. Plaintiffs provided the OSHA policies for the Clinic, Five Valleys, and Providence. Plaintiffs will follow up and see if there is another OSHA policy document for the Clinic within the limited timeframe, and if so, we will produce it to you.

Request for Production No. 16

We note that for the legal preemption issues before the Court, it matters not whether and to what extent individual facilities complied with the various changing laws, rules and requirements. Preemption is a matter of law for the Court to resolve. As for the request, this request seeks a very broad set of documents related to how the institutional Plaintiffs complied with the OSHA healthcare ETS in the midst of the unprecedented COVID-19 pandemic. In the early stages of the pandemic and throughout, circumstances changed on a daily basis. These entities were consumed with attempting to find a way to continue to treat their patients in a safe manner, keep their staff safe, and navigate the unprecedented challenges posed by the global pandemic during this time. Needless to say, it is almost impossible to identify any and all documents related to these issues. Nonetheless, Plaintiffs narrowed the request to the policies pertaining to the ETS and produced them.

Request for Production No. 17 and 18

These requests were not limited in time, and seek all documents "related to" compliance with CMS conditions of participation for hospitals that have been in effect for many years and subject to numerous compliance efforts. The request is exceedingly overbroad and Providence could not begin to respond to such an overly broad request. For example, 42 C.F.R. § 482.41 includes matters related to physical safety from fire, compliance with building codes, etc. Similarly, 42 C.F.R. § 482.41 is incredibly broad and Providence reasonably narrowed the request to a reasonable time period and produced its policies related to compliance with the CMS conditions of participation. Please explain why an expanded search is necessary, particularly given that this issue implicates a legal question of federal preemption and the nature of the requests do not appear to be calculated to lead to the discover of admissible evidence.

Request for Production No. 19

This request seeks all documents related to how each Plaintiff complies with the CMS COVID vaccine mandate applicable only to CMS participating hospitals. Not only is the request patently overbroad as drafted, it was objectionable on a number of other grounds. This new regulation was imposed around the same time as HB 702 was enacted. All documents related to compliance with the COVID vaccine mandate thereby implicates documents between Providence and legal counsel, which is why we objected to the request to the extent it seeks such documents. We limited the request as seeking policies only from Providence pertaining to infectious disease prevention, as noted in the response. Thereby, no specific documents were withheld as specifically responsive to this request. If you identify other specific documents that you are seeking, we can evaluate those requests.

Request for Production No. 20

The response to this request was handled in a similar manner. Communications with counsel regarding attempts at compliance with MCA § 49-2-312 are privileged. As with the prior request, the response to this request was limited to the non-objectionable portion of the request, and Plaintiffs produced the applicable policies of the Clinic, Five Valleys, and Providence.

Interrogatory No. 7

Plaintiffs maintain their objections to this request. As further discussed during the depositions of the Clinic, Five Valleys, and Providence, this request simply may not be answered. Plaintiffs took care to explain in detail why the request could not be answered. The request would require each entity to review every single patient record to make a determination as to "relative health status," which is a term too vague to facilitate a response in any event. We identified the average patient volumes of each facility to specifically show the sheer breadth and overly burdensome nature of the request, and to specifically support our objections. Providence has approximately 300,000 patient visits in a six-month period at St. Patrick Hospital, alone. Five Valleys has approximately 1,400 patient visits per month. The Clinic has approximately 385 patient visits per day. The information you have requested is not tracked and would require Plaintiffs to review every patient chart and then cross-reference all of the schedules and cancellations. Moreover, as explained during the depositions, patient status can change over time. You explored this issue in detail during the depositions of the Clinic, Five Valleys, and Providence. You have not identified any limitations that would make responding to this request possible.

Request for Production No. 22 and 24

Plaintiffs provided detailed objections to these requests. The requests are unclear and call for a legal conclusion to the extent it seeks reasonable accommodation requests "authorized under" MCA § 49-2-312. The reference to "reasonable accommodations" in the statute only applies, if at all, to Providence. This is made clear in our objections and response to the requests – the requests do not apply to the Clinic or Five Valleys. Further, "reasonable accommodations" is not defined in this context. As for Providence, we articulated the overbreadth and unduly burdensome nature of the request, given the manner in which Providence's written accommodation requests are maintained. Providence has 2,838 employee positions and does not track informal reasonable accommodation requests/responses, to the extent there may be any documents associated with those. As explained in these and other responses, formal written accommodation requests from employees are maintained by a third party administrator, and Providence had 193 cases (implicating many more documents) in the applicable time period. To respond to the request, Providence would need to review each of the 193 cases to determine whether the accommodation

request related to MCA § 49-2-312. Written accommodation requests from patients are noted in medical records, and requests from visitors and non-employees are maintained in an incident reporting system which does not allow searching or sorting of the requests based on the type or manner of request. We maintain these facts make this request overly burdensome and not proportional to the needs of this case as it pertains to Providence.

However, we had a productive discussion on these requests on our call today. Brent suggested a limited scope, or a solution whereby we acknowledge we will not seek to introduce a written accommodation request that was not disclosed. We would, of course, not attempt to use a document that was not provided to you. We will review Brent's suggestions and be back in touch with you on these two requests.

Request for Production No. 23

This request is objectionable on additional grounds, as noted in the response. The response remains objectionable as to Providence for the same reasons stated in the prior response. But as noted above, we will review and consider this response in light of Brent's suggested resolutions.

Five Valleys does not have responsive documents. The Clinic provided its reasonable accommodation requests. As to your note about the asserted confidentiality and privilege of private personnel information, the documents produced by the Clinic contained specific identities of employees. Employees have a privacy right in their personnel information, which they have not waived. This is the basis of the asserted objection, and we draw your attention to the entries on our privilege log noting redactions based on "private personnel information of nonparty."

Request for Production No. 25

Please see our prior responses and the objections contained in the responses. However, as it pertains to the Clinic and Five Valleys, these entities did not have formal, written accommodation requests by non-patients and non-employees, as provided in the response. As for Providence, we articulated the additional challenges associated with attempting to find specific documents in the general incident reporting process. We will, however, review in conjunction with the related requests noted above.

Request for Production No. 27

We are confirming, consistent with our response, that only Providence has had HRB claims filed against it under MCA § 49-2-312. As to the objections and claims of privilege, please see the entries on the privilege log for PL 1057-1085.

Request for Production No. 28

We are confirming, consistent with our response, that only Providence has had HRB claims filed against it under MCA § 49-2-312, and the Clinic and Five Valleys do not have "notices of non-compliance" to the extent we understood that term as noted in our response. We note that you did not provide any other definition for "notice of non-compliance" and we therefore assume that the definition articulated in the response is sufficient.

Request for Production No. 33 and 34

Plaintiffs limited the requests to the last three years such that policies pre-pandemic and current policies have been produced.

Request for Admission No. 4

This request does not seek an admission that the Clinic and Five Valleys do not operate as licensed "health care facilities" as defined in MCA § 50-5-101(26), as indicated by your letter. Instead, the plaint language of the request asked for an admission that these physician clinics "chose and continue to choose not to apply and operate" as such licensed facilities. We stand by our response and objection. This request is clearly argumentative. If, as you suggest in your letter, the purpose was to ascertain whether either operate as a "health care facility" as defined in MCA § 50-5-101(26), neither do. This was made clear in the depositions taken of the Clinic and Five Valleys. These entities operate as offices of private physicians.

Interrogatory No. 9 and 10

Plaintiffs maintain their objections to these requests. Hospitals and health care entities infection disease prevention protocols are extensive, particularly during these entities' response to the COVID-19 pandemic. As noted in the interrogatory, such protocols include immunizations, handwashing, sanitization of rooms/equipment, sanitization and cleaning of instruments, cleaning protocols, use of PPE, keeping ill individuals out of the care environment or limiting their access to others, health screenings, and ventilation, as well as individual provider recommendations. PPE itself is incredibly broad, as it includes gowns, shields, gloves, scrubs, masks, foot covers, goggles, hazmat suits, etc. For example, Providence is one of only a few hospitals in the nation that has care and isolation room, which is capable of treating patients with the most infectious diseases, in order to support Rocky Mountain Laboratories. There are multiple HEPA filters, specific ductwork, anterooms, surface modifications, full PPE suits, waste disposal protocols, sterilization protocols, etc. The formal policies and protocols are set forth in the documents provided, as noted in the response to this interrogatory. This subject matter was further explored

in the depositions of Five Valleys, the Clinic, and Providence. Plaintiffs have answered these interrogatories. It is unclear what further answer or information Defendants seek, particularly given the deposition testimony of the institutional Plaintiffs and the policies provided.

Request for Production No. 36

Plaintiffs have no further supplementation of this request for production at this time. Please see the response to the request and the documents produced, as well as our response noted above. If Defendants identify additional documents requested, Plaintiffs will consider such requests.

Interrogatory No. 11 and Request for Production No. 38

Plaintiffs cannot respond to this interrogatory given the overly broad and unduly burdensome nature of the request. The accompanying request for production carries the same challenges. The request asks for "every instance" over a more than four and a half year period in which "any Plaintiff" declined to refer a patient to another provider or facility due to the other provider's or facility's staff vaccination status. Construing the request only as applicable to the Clinic, Five Valleys, and Providence, the request still seeks a review of thousands upon thousands of patient interactions and most of those interactions would not be documented. Hundreds of individual providers are implicated as well. To explain the challenges with this request, Plaintiffs identified the total number of referring providers currently employed by the Clinic, Five Valleys and Providence and has identified an estimation of patient visits. This number increases significantly if we look back to January 1, 2018. Plaintiffs do not track this information in any obtainable format. We are unaware of any ability to respond to this request. However, you had the opportunity to depose these entities on this very topic, and they provided testimony in response to your questions.

Request for Production No. 39 and 40

Plaintiffs supplemented their responses to these to requests for production and provided additional documents that were located by MMA and Providence. Please see Plaintiffs Third Supplemental Responses to Defendants' First Combined Discovery Requests. Jean Branscum performed searches of her emails and MMA records for responsive documents. Following the discussion had on the record during Providence's deposition related to Providence's lobbying activities, Providence conducted additional searches for responsive documents, and identified the emails marked as PL 2007-2030, which have now been produced. As explained in Providence's deposition, Providence utilizes third party contractors in relation to this request. Moreover, it is unclear how this information is reasonably calculated to lead to the discovery of admissible evidence.

Request for Production No. 42

Contrary to your assertion, Plaintiffs very specifically explained their objections to this request, and we are happy to further explain the basis of our objections. Survey deficiencies as broadly used in the request could implicate the numerous requirements applicable to Five Valleys and the Clinic (as well as their physicians) related to the vast requirements for maintaining the ability to see and bill for Medicare and Medicaid patients. Moreover, Five Valleys and the Clinic have not put Medicare and Medicaid conditions of participation at issue in this litigation. The request, in relation to these entities, would be an improper fishing expedition. This is why we limited the request to Providence only, pertaining to what would amount to a formal survey deficiency under the specific conditions of participation related to a hospital (as the infectious disease CMS conditions of participation are what are at issue in this proceeding). Providence has not had any, but did provide the detailed Joint Commission survey which identifies specific items reviewed and addressed throughout that survey process. We are happy to have further dialogue regarding this request to see if we can come to a consensus as to what additional information is sought.

Request for Admission No. 7

We may need to have a conversation to ensure we are on the same page regarding this request and our response. Request for Admission No. 7 asked Plaintiffs to make an admission as to a partially quoted sentence taken from the cited federal register. The partial quote omitted both the introductory clause as well as the actual subject of the sentence. The partial quote, taken out of context, misconstrues what was stated in the federal register. Plaintiffs provided the entire quote. The actual text of the federal register is not at issue in this proceeding. For clarification, Plaintiffs admit that the language is a partial quote and admit that the actual text of the quote states:

> While we have not, until now, required any health care staff vaccinations, we have established, maintained, and regularly updated extensive health and safety requirements (CfCs, CoPs, requirements, etc.) for Medicare- and Medicaid- certified providers and suppliers.

86 Fed. Reg. 61568.

Request for Admission No. 8

Again, we invite a conversation so we can understand the dispute with Request for Admission No. 8. The claims in this lawsuit implicate federal preemption by federal laws. The conditions for participation in Medicare and Medicaid are established by CMS. Federal preemption lies in the CMS conditions of participation set forth in the application code of federal regulations.

Moreover, staff vaccination is both specifically required (i.e. the COVID vaccine requirement) and generally required under other applicable regulations. The request regarding conditions of participation set by DPHHS appears to confuse the entity responsible for setting the conditions of participation. Furthermore, this request is not limited in time and it is unknown what DPHHS has purported to do over the entirety of its existence. We are happy to further discuss so we may further understand Defendants' position on this request.

Interrogatory No. 12

Plaintiffs' response remains accurate. However, in a good faith attempt to provide additional information and avoid the need for individual depositions, Plaintiffs will follow up with the individual Plaintiffs to see if additional detail can be provided as to this response.

Interrogatory No. 13

"Other agencies" refers to CMS and the FDA, as well as professional organizations that have conducted the studies and findings as referenced in Plaintiffs' expert disclosures. Plaintiffs also refer Defendants to their initial disclosures.

Request for Production No. 44 and Interrogatory No. 14

In terms of providing responsive documents, Plaintiffs confirm their response to this request is accurate. However, as discussed during expert depositions, the experts draw from countless sources to inform and support their expert opinions. The specific studies cited to support the experts' opinions are identified in Plaintiffs Expert Disclosures, and to the extent additional studies will be relied upon, those will be identified. Additionally, Plaintiffs identified documents in their initial disclosures.

Very truly yours,

GARLINGTON, LOHN & ROBINSON, PLLP

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JKC:dvt

Exhibit 11

Morbidity and Mortality Weekly Report

Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems — United States, August 2022

Greta M. Massetti, PhD[1]; Brendan R. Jackson, MD[1]; John T. Brooks, MD[1]; Cria G. Perrine, PhD[1]; Erica Reott, MPH[1]; Aron J. Hall, DVM[1]; Debra Lubar, PhD[1]; Ian T. Williams, PhD[1]; Matthew D. Ritchey, DPT[1]; Pragna Patel, MD[1]; Leandris C. Liburd, PhD[1]; Barbara E. Mahon, MD[1]

On August 11, 2022, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

As SARS-CoV-2, the virus that causes COVID-19, continues to circulate globally, high levels of vaccine- and infection-induced immunity and the availability of effective treatments and prevention tools have substantially reduced the risk for medically significant COVID-19 illness (severe acute illness and post–COVID-19 conditions) and associated hospitalization and death (*1*). These circumstances now allow public health efforts to minimize the individual and societal health impacts of COVID-19 by focusing on sustainable measures to further reduce medically significant illness as well as to minimize strain on the health care system, while reducing barriers to social, educational, and economic activity (*2*). Individual risk for medically significant COVID-19 depends on a person's risk for exposure to SARS-CoV-2 and their risk for developing severe illness if infected (*3*). Exposure risk can be mitigated through nonpharmaceutical interventions, including improving ventilation, use of masks or respirators indoors, and testing (*4*). The risk for medically significant illness increases with age, disability status, and underlying medical conditions but is considerably reduced by immunity derived from vaccination, previous infection, or both, as well as timely access to effective biomedical prevention measures and treatments (*3*,*5*). CDC's public health recommendations change in response to evolving science, the availability of biomedical and public health tools, and changes in context, such as levels of immunity in the population and currently circulating variants. CDC recommends a strategic approach to minimizing the impact of COVID-19 on health and society that relies on vaccination and therapeutics to prevent severe illness; use of multicomponent prevention measures where feasible; and particular emphasis on protecting persons at high risk for severe illness. Efforts to expand access to vaccination and therapeutics, including the use of preexposure prophylaxis for persons who are immunocompromised, antiviral agents, and therapeutic monoclonal antibodies, should be intensified to reduce the risk for medically significant illness and death. Efforts to protect persons at high risk for severe illness must ensure that all persons have access to information to understand their individual risk, as well as efficient and equitable access to vaccination, therapeutics, testing, and other prevention measures. Current priorities for preventing medically significant illness should focus on ensuring that persons 1) understand their risk, 2) take steps to protect themselves and others through vaccines, therapeutics, and nonpharmaceutical interventions when needed, 3) receive testing and wear masks if they have been exposed, and 4) receive testing if they are symptomatic, and isolate for ≥5 days if they are infected.

Vaccines and Therapeutics To Reduce Medically Significant Illness

COVID-19 vaccination. COVID-19 vaccines are highly protective against severe illness and death and provide a lesser degree of protection against asymptomatic and mild infection (*6*). Receipt of a primary series alone, in the absence of being up to date with vaccination* through receipt of all recommended booster doses, provides minimal protection against infection and transmission (*3*,*6*). Being up to date with vaccination provides a transient period of increased protection against infection and transmission after the most recent dose, although protection can wane over time. The rates of COVID-19–associated hospitalization and death are substantially higher among unvaccinated adults than among those who are up to date with recommended COVID-19 vaccination, particularly adults aged ≥65 years (*5*,*7*). Emerging evidence suggests that vaccination before infection also provides some protection against post–COVID-19 conditions,† and that vaccination among persons with post–COVID-19 conditions might help reduce their symptoms (*8*). Continuing to increase vaccination coverage and ensuring that persons are up to date with vaccination are essential to preventing severe outcomes. Overall booster dose coverage in the United States remains low,§ which is concerning given the meaningful reductions in risk for severe illness and death that booster doses provide and the importance of booster doses to counter waning of vaccine-induced immunity. Public health efforts to expand reach and promote equitable access to vaccination have resulted in similar rates of

* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html
† Vaccination is also effective in preventing multisystem inflammatory syndrome in children, a rare but severe postinfectious hyperinflammatory condition that can occur after mild or asymptomatic infection among children. https://www.cdc.gov/mmwr/volumes/71/wr/mm7102e1.htm
§ https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-additional-dose-totalpop

primary series coverage across most racial and ethnic groups (*9*); however, racial and ethnic disparities in booster coverage have emerged (*10*). Supporting community partnerships and leveraging trusted sources of information must continue in order to eliminate persistent disparities and achieve equity in booster dose coverage, including through increasing education efforts and promotion of equitable vaccination outreach. Public health efforts need to continue to promote up-to-date vaccination for everyone, especially with vaccines targeting emerging novel variants that might be more transmissible or immune-evasive.

Preexposure prophylaxis. COVID-19 vaccine effectiveness against severe outcomes is lower in persons who are immunocompromised than in those who are not, and persons who are immunocompromised and have COVID-19 are at increased risk for intensive care unit admission and death while hospitalized, irrespective of their vaccination status (*11*,*12*). Preexposure prophylaxis with Evusheld[¶] can help protect persons with moderate to severe immunocompromise who might not mount an adequate immune response after COVID-19 vaccination, as well as persons for whom COVID-19 vaccination is not recommended because of their personal risk for severe adverse reactions. In addition to early antiviral treatment if infected, persons who are moderately or severely immunocompromised can benefit from COVID-19 preexposure prophylactic medication to help prevent severe COVID-19 illness, as an adjunct to up-to-date vaccination for themselves and their close contacts, early testing, nonpharmaceutical interventions, and prompt access to treatment if they are infected.

Medications to treat COVID-19. Antiviral medications (Lagevrio [molnupiravir], Paxlovid [nirmatrelvir and ritonavir], and Veklury [remdesivir]) and monoclonal antibodies (bebtelovimab) are available to treat COVID-19 in persons who are at increased risk for severe illness,[**] including older adults, unvaccinated persons, and those with certain medical conditions[††] (*13*). Antiviral agents reduce risk for hospitalization and death when administered soon after diagnosis. The federal Test to Treat initiative facilitates rapid, no-cost access to oral COVID-19 treatment for eligible persons who receive a positive SARS-CoV-2 test result.[§§] Recent expansion of prescribing authority of Paxlovid to pharmacists intends to further facilitate access.[¶¶] Continued efforts are needed to reduce racial and ethnic differences in receipt of monoclonal antibody therapies (*14*) and disparities in dispensing rates for oral antiviral prescriptions by community social vulnerability (*15*).

COVID-19 Prevention Strategies

Monitoring COVID-19 Community Levels to guide COVID-19 prevention efforts. Persons can use information about the current level of COVID-19 impact on their community to decide which prevention behaviors to use and when (at all times or at specific times), based on their own risk for severe illness and that of members of their household, their risk tolerance, and setting-specific factors. CDC's COVID-19 Community Levels reflect the current effect of COVID-19 on communities and identify geographic areas that might experience increases in severe COVID-19–related outcomes, based on hospitalization rates, hospital bed occupancy, and COVID-19 incidence during the preceding period[***] (*1*). Prevention recommendations based on COVID-19 Community Levels have the explicit goals of reducing medically significant illness and limiting strain on the health care system. At all COVID-19 Community Levels (low, medium, and high), recommendations emphasize staying up to date with vaccination, improving ventilation, testing persons who are symptomatic and those who have been exposed, and isolating infected persons. At the medium COVID-19 Community Level, recommended strategies include adding protections for persons who are at high risk for severe illness (e.g., use of masks or respirators that provide a higher level of wearer protection). At the high COVID-19 Community Level, additional recommendations focus on all persons wearing masks indoors in public and further increasing protection to populations at high risk.[†††] As SARS-CoV-2 continues to circulate, changes

[¶] Adults and adolescents aged ≥12 years might be eligible for Evusheld, a combination of two monoclonal antibodies (tixagevimab copackaged with cilgavimab, administered as two consecutive intramuscular injections), if they are moderately or severely immunocompromised and might not mount an adequate immune response to COVID-19 vaccination or have a history of severe allergic reactions to COVID-19 vaccines, and do not currently have COVID-19 and have not recently had close contact with someone with COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#preventive; https://www.fda.gov/media/154701/download

[**] Paxlovid, which is taken orally, and remdesivir, administered intravenously, are the current primary treatments, with Lagevrio and monoclonal antibodies as alternates (https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/). Some patients who have completed a 5-day course of Paxlovid and have recovered can experience recurrent illness; patients experiencing COVID-19 rebound should be advised to follow CDC's recommendations for isolation (https://emergency.cdc.gov/han/2022/pdf/CDC_HAN_467.pdf).

[††] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

[§§] https://aspr.hhs.gov/TestToTreat/Pages/default.aspx

[¶¶] https://www.fda.gov/media/155049/download

[***] CDC recommends the use of three indicators to measure COVID-19 Community Levels: 1) new COVID-19 hospital admissions per 100,000 population in the last 7 days; 2) percentage of staffed inpatient beds occupied by patients with confirmed COVID-19 (7-day average); and 3) new COVID-19 cases per 100,000 population in the last 7 days. The COVID-19 Community Level is determined by the higher of the new admissions and inpatient beds occupied metrics, based on the current level of new cases per 100,000 population in the last 7 days. The indicators combine to result in three COVID-19 Community Levels: low, medium, and high. COVID-19 Community Levels do not apply in health care settings, such as hospitals and nursing homes. Performance of COVID-19 Community Levels (including the component metrics and performance overall) will be reassessed and adjusted, if necessary, to accommodate changes in factors such as viral dynamics, emergence of novel variants of concern, or ecological changes that affect indicator data (e.g., shifts to greater use of self-testing or changes in reporting cadence).

[†††] Recommendations are additive, in that recommendations for the low community level apply to the medium and high levels, and the additional recommendations for medium level apply to the high level.

in COVID-19 Community Levels for a jurisdiction help signal when use of some prevention strategies should be discontinued or increased, based on an individual person's level of risk for severe illness or that of their household or social contacts. The COVID-19 Community Levels provide a broad framework for public health officials and jurisdictions to use and adapt as needed based on local context by combining local information to assess the need for public health interventions.

Nonpharmaceutical interventions. Implementation of multiple prevention strategies helps protect individual persons and communities from SARS-CoV-2 exposure and reduce risk for medically significant illness and death by reducing risk for infection (Table). Implementation of multiple nonpharmaceutical preventive interventions can complement use of vaccines and therapeutics, especially as COVID-19 Community Levels increase and among persons at high risk for severe illness. CDC's COVID-19 prevention recommendations no longer differentiate based on a person's vaccination status because breakthrough infections occur, though they are generally mild (*16*), and persons who have had COVID-19 but are not vaccinated have some degree of protection against severe illness from their previous infection (*17*). In addition to strategies recommended at all COVID-19 Community Levels, education and messaging to help individual persons understand their risk for medically significant illness complements recommendations for prevention strategies based on risk.

Testing for current infection. Diagnostic testing can identify infections early so that infected persons can take action to reduce their risk for transmitting virus and receive treatment, if clinically indicated, to reduce their risk for severe illness and death. All persons should seek testing for active infection when they are symptomatic or if they have a known or suspected exposure to someone with COVID-19. When considering whether and where to implement screening testing of asymptomatic persons with no known exposure, public health officials might consider prioritizing high-risk congregate settings, such as long-term care facilities, homeless shelters, and correctional facilities, and workplace settings that include congregate housing with limited access to medical care.§§§ In these types of high-risk congregate settings, screening testing might complement diagnostic testing of symptomatic persons by identifying asymptomatic infected persons (*18,19*). When implemented, screening testing strategies should include all persons, irrespective of vaccination status. Screening testing might not be cost-effective in general community settings, especially if COVID-19 prevalence is low (*20,21*).

Isolation. Symptomatic or infected persons should isolate promptly, and infected persons should remain in isolation for ≥5 days and wear a well-fitting and high-quality mask or respirator if they must be around others. Infected persons may end isolation after 5 days, only when they are without a fever for ≥24 hours without the use of medication and all other symptoms have improved, and they should continue to wear a mask or respirator around others at home and in public through day 10¶¶¶ (Figure) (*22,23*). Persons who have access to antigen tests and who choose to use testing to determine when they can discontinue masking should wait to take the first test until at least day 6 and they are without a fever for ≥24 hours without the use of fever-reducing medication and all other symptoms have improved. Use of two antigen tests with ≥48 hours between tests provides more reliable information because of improved test sensitivity (*24*). Two consecutive test results must be negative for persons to discontinue masking. If either test result is positive, persons should continue to wear a mask around others and continue testing every 48 hours until they have two sequential negative results.****

Managing SARS-CoV-2 exposures. CDC now recommends case investigation and contact tracing only in health care settings and certain high-risk congregate settings.†††† In all other circumstances, public health efforts can focus on

§§§ In high-risk settings such as nursing homes, modeling suggests that serial screening testing might be effective when performed very frequently (e.g., daily), although such high frequency is likely logistically challenging. https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciac505/6611848

¶¶¶ Persons at high risk of severe illness should wear masks or respirators (N95/KN95s) that provide more protection indoors in public at medium and high COVID-19 Community Levels. All persons should wear well-fitting masks or respirators indoors in public at high COVID-19 Community Levels (https://www.cdc.gov/coronavirus/2019-ncov/your-health/covid-by-county.html). Persons who had moderate illness from COVID-19, including those who show evidence of lower respiratory illness such as shortness of breath or difficulty breathing, should isolate for ≥10 days. Persons who had severe illness from COVID-19, including those who were hospitalized and those who required intensive care or mechanical ventilation, and persons with immunocompromising conditions should isolate for ≥10 days and talk with a health care provider to determine end of isolation. https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/

**** Persons who choose to use testing to determine when to discontinue masking can end isolation after day 5 even if they receive a positive test result. They should continue wearing a well-fitting and high-quality mask around others at home and in public until they receive two consecutive negative test results, with tests taken ≥48 hours apart. For some persons, this might mean that they will continue masking longer than 10 days since symptom onset. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2

†††† Case investigation and contact tracing are fundamental activities that involve working with a patient (symptomatic or asymptomatic) who has received a diagnosis of an infectious disease to identify and provide support to persons (contacts) who might have been infected through exposure to the patient. CDC recommends that health departments prioritize case investigation and contact tracing in high-risk congregate settings, for clusters or outbreaks that involve unusual clusters of cases, or for novel or emerging variants that might pose significant risks for severe illness, hospitalization, or death. https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/prioritization.html

TABLE. Person- and community-level public health strategies to minimize the impact of COVID-19 on individual persons, communities, and health care systems — United States, August 2022

Recommended public health strategy	Person- and household-level prevention behaviors	Community-level prevention strategies*	Links to guidance and scientific evidence
COVID-19 vaccination	Stay up to date with COVID-19 vaccination	Distribute and administer vaccines to achieve high community vaccination coverage and ensure health equity Support community partnerships and leverage trusted sources of information to expand booster coverage	Vaccines for COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html Stay up to date with COVID-19 vaccines: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html Science brief: COVID-19 vaccines and vaccination: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html
Preexposure prophylaxis	Persons who are moderately or severely immunocompromised might benefit from COVID-19 preexposure prophylactic treatment (Evusheld) to prevent severe COVID-19 illness	Provide education and communication outreach to patients and clinical care organizations that serve patients with immunocompromising conditions to support equitable access to preexposure prophylaxis	COVID-19 preventive medication: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#preventive Prevention of SARS-CoV-2 infection: https://www.covid19treatmentguidelines.nih.gov/overview/prevention-of-sars-cov-2/
Medications for treatment of COVID-19	Persons at increased risk for severe illness should have a plan for rapid access to tests and treatment if they become infected	Enable rapid access to oral COVID-19 treatment within ≤5 days of diagnosis Support clinical-community linkages to ensure access to antiviral and monoclonal antibody treatment and reduce health disparities	COVID-19 treatments and medication: https://www.cdc.gov/coronavirus/2019-ncov/your-health/treatments-for-severe-illness.html Clinical management of COVID-19: https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/
Improved ventilation	Increase ventilation and filtration	Take steps to increase ventilation and filtration in public places	Improving ventilation in your home: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/Improving-Ventilation-Home.html Ventilation in buildings: https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html Ventilation in schools and childcare programs: https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/ventilation.html Science brief: SARS-CoV-2 transmission: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html
Masks and respirators	Persons at high risk for severe illness should wear a mask or respirator (N95/KN95) that provides more protection indoors in public at medium and high COVID-19 community levels All persons should wear well-fitting masks or respirators indoors in public at high COVID-19 Community Levels†	Recommend all persons wear well-fitting masks or respirators at high COVID-19 Community Levels and support use of masks through messaging and resources	Masks and respirators: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html Science brief: community use of masks to control and spread of SARS-CoV-2: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/masking-science-sars-cov2.html
Testing	Persons with a known or suspected exposure to someone with COVID-19 and those who experience symptoms should promptly seek testing through point-of-care and at-home tests	Increase equitable access to testing, including through point-of-care and at-home tests for all persons Recommend use of screening testing in certain high-risk settings (e.g., long-term care facilities or correctional facilities) to reduce risks of outbreaks Support Test to Treat and other initiatives to support rapid access to treatment among persons at high risk for severe illness	Overview of testing for SARS-CoV-2: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html Technical page: guidance for healthcare workers about COVID-19 (SARS-CoV-2) testing: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing.html

See table footnotes on the next page.

TABLE. (*Continued*) Person- and community-level public health strategies to minimize the impact of COVID-19 on individual persons, communities, and health care systems — United States, August 2022

Recommended public health strategy	Person- and household-level prevention behaviors	Community-level prevention strategies*	Links to guidance and scientific evidence
Isolation	Symptomatic persons should isolate promptly and seek testing Infected persons should stay home for ≥5 days; for 10 days, infected persons should wear a mask around others at home and in public and avoid contact with persons at high risk for severe illness¶	Increase equitable access to testing, including through point-of-care and at-home tests for all persons Support case investigation and contact tracing in high-risk settings where recommended	Isolation: https://www.cdc.gov/coronavirus/2019-ncov/your-health/isolation.html Science brief: SARS-CoV-2 transmission: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html
Managing exposures to SARS-CoV-2	Persons with recent exposure should wear a mask indoors in public for 10 days and test ≥5 days after last exposure	Increase equitable access to testing, including through point-of-care and at-home tests for all persons Support case investigation and contact tracing in high-risk settings where recommended§	What to do if you are exposed: https://www.cdc.gov/coronavirus/2019-ncov/your-health/if-you-were-exposed.html Definition of close contacts: https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html#contact Science brief: SARS-CoV-2 transmission: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html
Hand hygiene	Wash hands frequently	Ensure provision of adequate hand sanitation supplies	How to protect yourself and others: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html Science brief: SARS-CoV-2 transmission: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html
Increasing space and distance	Persons at high risk for severe illness can consider avoiding crowded areas and minimizing direct physical contact, especially in settings where there is high risk for exposure	Provide education to populations at high risk for severe illness to advise them to consider taking steps to protect themselves in settings where there is high risk for exposure	How to protect yourself and others: https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html Science brief: SARS-CoV-2 transmission: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html

* Recommended strategies relate to general community settings; adapted setting-specific guidance and recommendations include schools and early childhood settings (https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-childcare-guidance.html), high-risk congregate settings such as correctional facilities and homeless shelters (https://www.cdc.gov/coronavirus/2019-ncov/community/high-risk-congregate-settings.html), health care settings (https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html), and travel (https://www.cdc.gov/coronavirus/2019-ncov/travelers/index.html).

† Although all masks and respirators provide some level of protection, properly fitting respirators provide the highest level of protection. Persons may consider the situation and other factors when choosing a mask or respirator that offers greater protection. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html#DifferentSituations

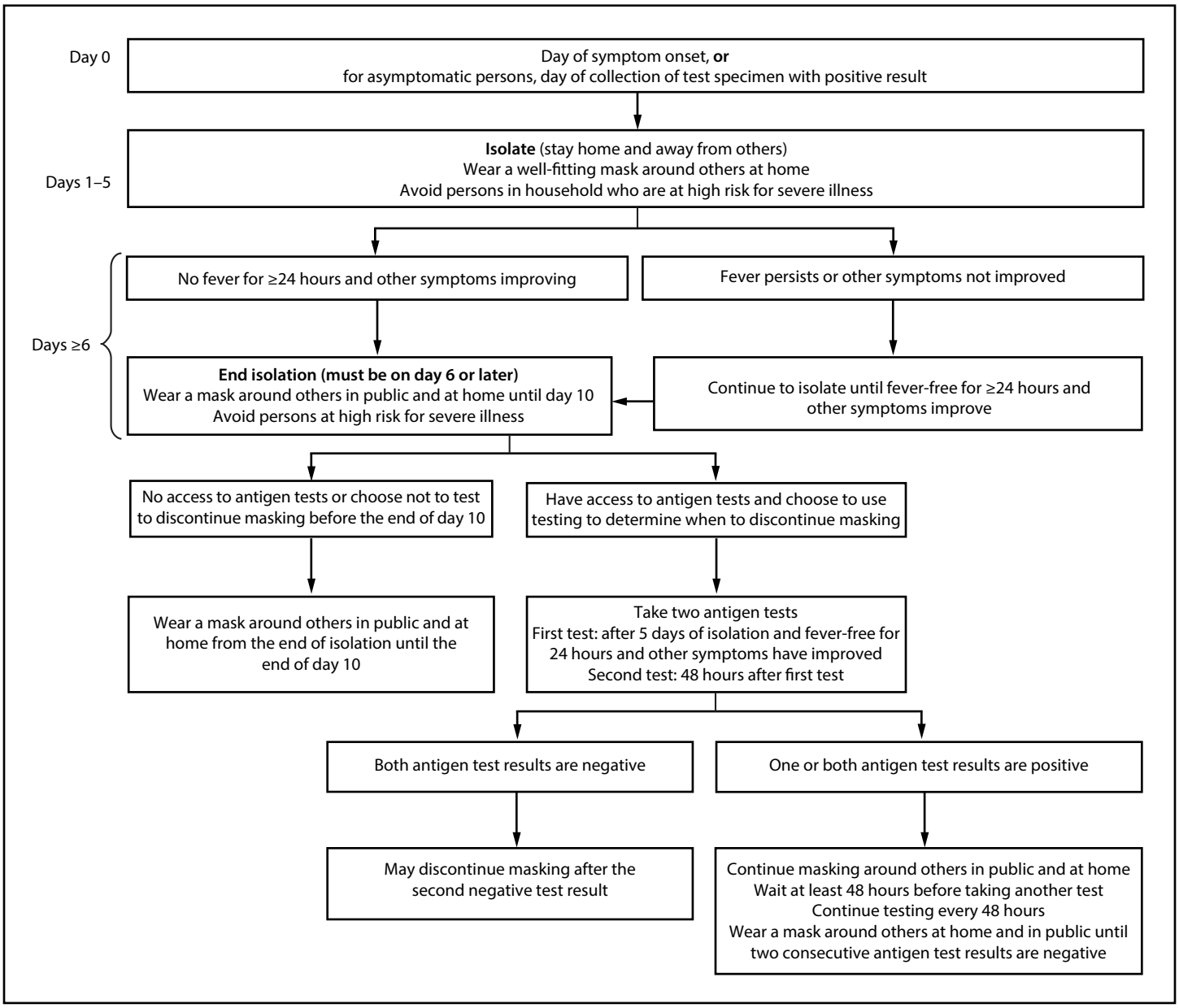
§ Universal case investigation and contact tracing are not recommended for COVID-19; health departments and jurisdictions should prioritize investigation of COVID-19 cases, clusters, and outbreaks involving high-risk congregate settings such as long-term care facilities and correctional facilities or unusual clusters of cases. https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/prioritization.html

¶ Infected persons should end isolation only when they are without a fever for ≥24 hours without use of medication and all other symptoms have improved. Persons who had moderate illness from COVID-19, including those who show evidence of lower respiratory disease such as shortness of breath or difficulty breathing should isolate for ≥10 days. Persons who had severe illness from COVID-19 (including those who were hospitalized or required intensive care) and persons who are immunocompromised should consult with a health care provider about how to determine end of isolation. https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/

case notification and provision of information and resources to exposed persons about access to testing. Persons who have had recent confirmed or suspected exposure to an infected person should wear a mask for 10 days around others when indoors in public and should receive testing ≥5 days after exposure (or sooner, if they are symptomatic), irrespective of their vaccination status.[§§§§] In light of high population levels of anti–SARS-CoV-2 seroprevalence (*7*,*16*), and to limit social

[§§§§] For persons unable to wear a mask or children aged <2 years, other prevention actions should be taken, such as additional physical distancing and increased ventilation. Exposed persons who develop symptoms should receive testing promptly.

FIGURE. Recommendations for isolation,* masking,† and additional precautions for persons with COVID-19 illness§ or who receive a positive SARS-CoV-2 test result¶, — United States, August 2022**



* Symptomatic persons should isolate immediately and get tested. They should remain in isolation until they receive a test result. If the test result is positive, they should follow the full isolation recommendations. Asymptomatic persons should begin counting isolation from the first full day after a positive test result (day 0 is the date the test specimen was collected). If an infected person develops symptoms after a positive test result, the isolation count starts again with day 0 being the first day of symptoms.

† Persons at high risk for severe illness should wear a mask or respirator (N95/KN95) that provides more protection indoors in public at medium and high COVID-19 Community Levels. All persons should wear well-fitting masks or respirators indoors in public at high COVID-19 Community Levels. https://www.cdc.gov/coronavirus/2019-ncov/your-health/covid-by-county.html

§ Persons who had moderate illness from COVID-19, including those who show evidence of lower respiratory disease such as shortness of breath or difficulty breathing should isolate for ≥10 days. Persons who had severe illness from COVID-19, including those who were hospitalized and those who required intensive care or mechanical ventilation, and persons with immunocompromising conditions should isolate for ≥10 days and consult with a health care provider to determine end of isolation. https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/

¶ Infected persons can contact their health care provider to discuss their test results and available treatment options. They should monitor fever and other symptoms. If they develop an emergency warning sign, they should seek emergency medical care immediately. Emergency warning signs include trouble breathing; persistent pain or pressure in chest; new confusion; inability to awaken or stay awake; and pale, gray, or blue-colored skin, lips, or nailbeds, depending on skin tone. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

** If symptoms worsen from the end of isolation through day 10, infected persons should restart isolation; they should consider consulting with a health care provider to determine care.

Summary

What is already known about this topic?

High levels of immunity and availability of effective COVID-19 prevention and management tools have reduced the risk for medically significant illness and death.

What is added by this report?

To prevent medically significant COVID-19 illness and death, persons must understand their risk, take steps to protect themselves and others with vaccines, therapeutics, and nonpharmaceutical interventions when needed, receive testing and wear masks when exposed, receive testing if symptomatic, and isolate for ≥5 days if infected.

What are the implications for public health practice?

Medically significant illness, death, and health care system strain can be reduced through vaccination and therapeutics to prevent severe illness, complemented by use of multiple prevention methods to reduce exposure risk and an emphasis on protecting persons at high risk for severe illness.

and economic impacts, quarantine of exposed persons is no longer recommended, regardless of vaccination status.

Protecting Persons Most at Risk for Severe Illness

Multiple nonpharmaceutical and medical prevention measures are available to substantially reduce the risk for medically significant illness and death among persons at particularly high risk for these outcomes because of older age, disability, moderate or severe immunocompromise (*25*), or other underlying medical conditions (including pregnancy) (*26*). In addition to recommending that persons stay up to date with vaccination, public health strategies to protect persons at high risk include use of masks or respirators (i.e., specialized filtering masks such as N95/KN95s) that provide more protection for the wearer,[¶¶¶¶] preexposure prophylaxis if indicated (e.g., for persons who are immunocompromised), and early access to and use of antivirals. At medium and high COVID-19 Community Levels, persons at high risk for severe illness and their contacts should consider wearing well-fitting masks or respirators that provide more protection to the wearer because of better filtration and fit to reduce exposure and infection risk. Persons who have household or social contact with persons at high risk should consider self-testing to detect infection before contact at medium and high COVID-19 Community Levels. Public health efforts should promote health equity by purposefully reaching out to all populations at high risk for severe illness to broaden access to preexposure prophylaxis, testing, and oral antivirals. Public health practitioners and organizations should consider the characteristics of their local or setting-specific populations when determining whether to strengthen or add prevention strategies that supplement disease control efforts and protect those persons at highest risk for severe illness or death. Strengthening public health communications and messaging can also help persons assess their personal level of risk for severe illness and use that knowledge to choose preventive behaviors to protect themselves and those around them.[*****]

[¶¶¶¶] Masks and respirators can provide different levels of protection depending on the type of mask and how they are used. Loosely woven cloth products provide the least protection, layered finely woven products offer more protection, well-fitting disposable surgical masks and KN95s offer even more protection, and well-fitting CDC National Institute for Occupational Safety and Health–approved respirators (including N95s) offer the highest level of protection. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html#DifferentSituations

Discussion

COVID-19 remains an ongoing public health threat; however, high levels of vaccine- and infection-induced immunity and the availability of medical and nonpharmaceutical interventions have substantially reduced the risk for medically significant illness, hospitalization, and death from COVID-19. As transmission of SARS-CoV-2 continues, the current focus on reducing medically significant illness, death, and health care system strain are appropriate and achievable aims that are supported by the broad availability of the current suite of effective public health tools. Rapid identification of emergent variants necessitating a shift in prevention strategy makes continued detection, monitoring, and characterization of novel SARS-CoV-2 variants essential. Incorporating actions to mitigate the impact of COVID-19 into long-term sustainable routine practices is imperative for society and public health.

[*****] https://www.cdc.gov/coronavirus/2019-ncov/your-health/factors-affecting-risk-of-getting-sick.html

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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