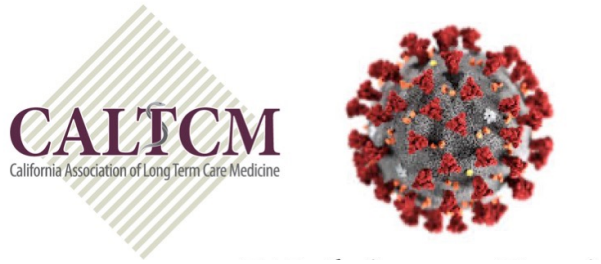

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COVID-19 Webinar Series

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Patricia Latham Bach, PsyD, RN
Heather D'Adamo, MD, CMD
Janice Hoffman-Simen, Pharm.D., EdD, APh, BCGP, FASCP
Ashkan Javaheri, MD
Pouria Kashkouli, MD
Albert Lam, MD
Dominic Lim, MPH
Karl Steinberg, MD, CMD, HMDC
Michael Wasserman, MD, CMD

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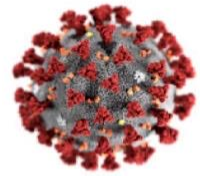

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Clinical Psychologist; Assistant Professor Eastern VA Med School; Chaplain, Placer County Law Enforcement Chaplaincy

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Webinar Faculty

Alex Bardakh, MPP, PLC

Director of Public Policy

AMDA-The Society for Post-Acute and Long-Term Care Medicine (AMDA)

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Webinar Faculty

Ashkan Javaheri, MD, CMD

Geriatrician

Mercy Medical Group–Dignity Health Medical Foundation

Head of the Geriatric Division, Associate Clinical Professor, UC Davis School of Medicine

Sacramento, CA

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Webinar Faculty

Jane D.Siegel, MD

PHMO III Healthcare-Associated Infections Program

California Department of Public Health

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Webinar Faculty

Karl E. Steinberg, MD, CMD, HMDC

Immediate Past-President, AMDA: The Society for Post-Acute and Long-Term Care Medicine

CALTCM BOD Member & Past-President

Chief Medical Officer, Mariner Health Care

Chief Medical Officer, Beecan Health

Oceanside, CA

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A Breath of Fresh Air
Discussing Ventilation,
Boosters, and Waivers

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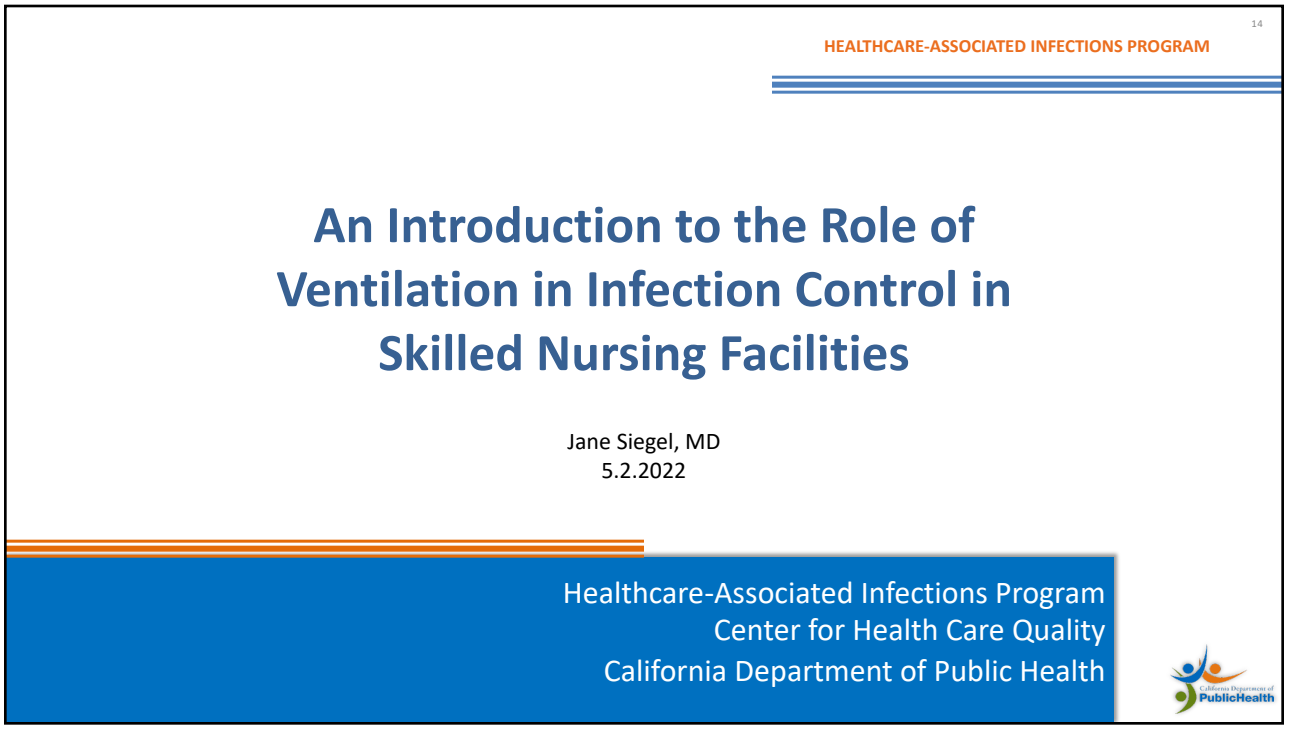
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HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM
An Introduction to the Role of Ventilation in Infection Control in Skilled Nursing Facilities
Jane Siegel, MD
5.2.2022
Healthcare-Associated Infections Program
Center for Health Care Quality
California Department of Public Health

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HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM

Objectives

- Review the routes of transmission of SARS-CoV-2
- Understand basic ventilation principles as they relate to skilled nursing facilities
- Consideration of additional education on the role of ventilation in preventing transmission of respiratory tract pathogens SNF and engaging with team to assess ventilation in your facilities

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HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM

Routes of Transmission of SARS-CoV-2

- The principal mode by which people are infected with SARS-CoV-2 (the virus that causes COVID-19) is through **exposure to respiratory fluids carrying infectious virus**
- 3 principal ways of exposure:
  - **Inhalation** of very fine respiratory droplets and aerosol particles
  - **Deposition** of respiratory droplets and particles on exposed mucous membranes in the mouth, nose, or eye by direct splashes and sprays
  - **Touching** mucous membranes with hands that have been soiled either directly by virus-containing respiratory fluids or indirectly by touching surfaces with virus on them.

CDC Science Brief 5/7/2021

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HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM

Risk of Transmission

- Varies according to **amount of virus** to which one is exposed
  - Larger, heavier respiratory droplets fall to ground, leaving very fine droplets and aerosol particles that remain in the airstream and progressively mix with, and become diluted within, the growing volume and streams of air they encounter
  - Progressive loss of viral viability and infectiousness influenced by temperature, humidity, sunlight
  - Increased exhalation
  - Prolonged exposure
  - Enclosed air spaces with inadequate ventilation to clear virus-containing particles
  - Distance most often within 6 feet, but may be farther

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HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM

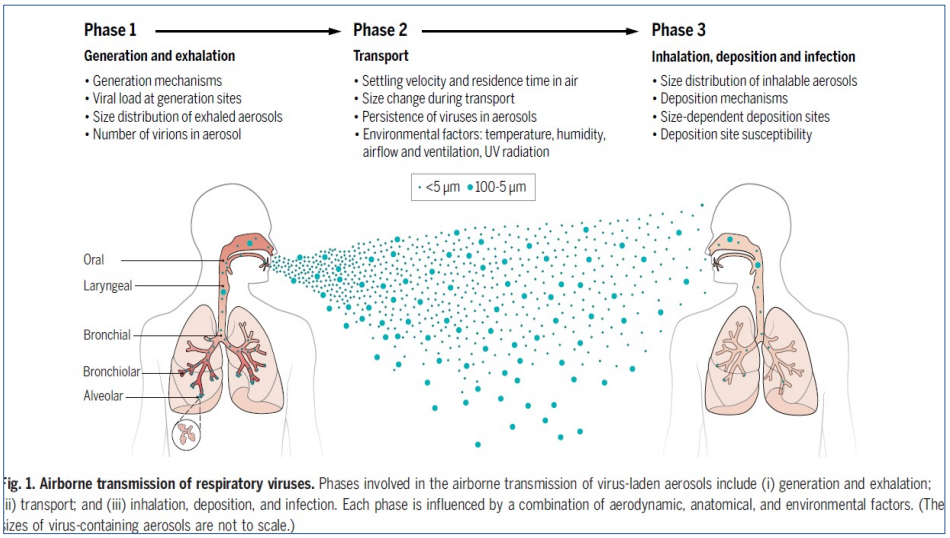

Fig. 1. Airborne transmission of respiratory viruses. Phases involved in the airborne transmission of virus-laden aerosols include (i) generation and exhalation; (ii) transport; and (iii) inhalation, deposition, and infection. Each phase is influenced by a combination of aerodynamic, anatomical, and environmental factors. (The sizes of virus-containing aerosols are not to scale.)

Wang CC. Science 8.27.2021; doi.org/10.1126/science.abd9149

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Table. New Insights Into Respiratory Virus Transmission and Potential Implications for Infection Control Policies

Traditional Teaching	Current Understanding	Potential Policy Responses
Some respiratory pathogens are transmitted via aerosols (e.g., measles, tuberculosis), and some are transmitted by droplets (e.g., influenza and other respiratory viruses). Medical masks provide sufficient protection against "droplet" pathogens. Respirators are only necessary for "aerosol" pathogens.	All respiratory viruses can be transmitted by aerosols (11–18). People emit respiratory particles in a continuous range of sizes. There is no sharp dividing line between aerosols and droplets (3–6). Most respiratory emissions are aerosols (3). Medical masks decrease but do not eliminate transmission of respiratory viruses and tuberculosis (50, 66–68).	Consider creating a uniform set of respiratory precautions for all respiratory pathogens rather than differentiating between airborne vs. droplet pathogens. Consider using higher-level respiratory protection (e.g., N95 respirators) in the care of all patients with active respiratory viral infections. Prioritize airborne-infection isolation rooms for pathogens historically associated with long-range transmission and for patients with high viral loads.
Droplet-borne pathogens only present a risk for short-range transmission. Aerosol-borne pathogens are frequently transmitted over long distances, and failure to observe long-distance transmission indicates absence of transmission by aerosols.	Risk for transmission of aerosol-borne pathogens is greatest immediately adjacent to the source (28, 29, 31). Risk diminishes with distance due to diffusion and dilution (28, 29, 31). Risk increases with time due to cumulative exposure (28, 29, 31). Long-range transmission is primarily associated with poor ventilation because it allows for accumulation of virus-borne aerosols (32–36).	Reinforce minimum ventilation standards for clinical spaces. Consider increasing minimum ventilation standards for nonclinical spaces. Consider using higher-level respiratory protection, such as N95 respirators, for all prolonged, face-to-face encounters when the community incidence of SARS-CoV-2 (or other respiratory viruses) is high. Consider using upper-room or 222-nm ultraviolet air disinfection or HEPA filters to decrease transmission risk in inadequately ventilated spaces.
Selected procedures ("aerosol-generating procedures") increase aerosol production and therefore require higher-level protection to prevent transmission (respirators and airborne-infection isolation rooms).	Most procedures do not meaningfully increase respiratory aerosols (60–64). Talking, exercise, heavy breathing, coughing, and singing do increase aerosol generation (6–8).	Consider retiring the concept of aerosol-generating procedures. Risk-stratify patients instead on the basis of viral load, severity of illness, or anticipated duration of an encounter and likely proximity to the respiratory tract.

HEPA = high-efficiency particulate air.

Klompas M. Ann Intern Med 2021 Dec;174(12):1710-1718. doi: 10.7326/M21-2780.

Ventilation Principles

- Benefits of an effective ventilation system are greater than thermal comfort
  - Improvement of ventilation systems provides benefits of good risk management and a proactive approach to reducing risks of transmission of SARS-CoV-2 and other respiratory tract pathogens
  - Assessment of ventilation is recognized as an important component of infection prevention and control programs in healthcare facilities
- HICPAC/CDC is reviewing routes of transmission of infectious agents and may be considering revising the droplet, contact, airborne framework to fit real world conditions

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HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM

CDPH Resources

- Each SNF varies in their air handling systems, determined in part by age of the building; ACH requirement in resident rooms SNF = 2*
- CDPH Occupational Health Branch Industrial Hygienists (IH)
  - Rob Stepp, Kyle Peerless, Elon Ullman
  - Visits to SNF, schools, correctional facilities to assess ventilation systems and provide recommendations
  - Working with IPs in SNF, LHD, HAI to educate on role of ventilation in infection control
  - Available to assess SNF to provide recommendations for improvement in ventilation that reflect best practice
- CDPH has formed an Indoor Air Quality (IAQ) committee
- Medical directors may have opportunities to support efforts to reduce risk of transmission of infectious agents

* Per ASHRAE standard 170-2021

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HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM

Tools to Improve Ventilation in Buildings

- Increase introduction of outside air; should be filtered
- Ensure ventilation systems operate properly and provide acceptable indoor air quality for the current occupancy level for each space.
- Rebalance or adjust HVAC systems to increase total airflow to occupied spaces when possible.
- Turn off any demand-controlled ventilation (DCV) controls that reduce air supply based on occupancy or temperature during occupied hours
- Ensure restroom exhaust fans are functional and operating at full capacity when the building is occupied.

www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html; see tools and FAQs

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HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM

Tools to Improve Ventilation in Buildings (cont'd.)

- Improve central air filtration:
  - Increase air filtration to as high as possible without significantly reducing design airflow. MERV ≥ 13 recommended for healthcare facilities. Increased filtration efficiency is especially helpful when enhanced outdoor air delivery options are limited.
  - Make sure air filters are properly sized and within their recommended service life.
  - Inspect filter housing and racks to ensure appropriate filter fit and minimize air that flows around, instead of through, the filter.

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HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM

Tools to Improve Ventilation in Buildings (cont'd.)

- Inspect and maintain HVAC systems according to manufacturer's instructions.
- Use portable air cleaners for auxiliary air cleaning.
- Generate clean-to-less-clean air movement by evaluating and repositioning as necessary, the supply louvers, exhaust air grilles, and/or damper settings. Measure direction of airflow using tissue test, smoke tubes or handheld pressure monitor.
- Consider use of portable CO2 monitors (Donskey CJ. ICHE 2022; doi:10.1017/ice.2022.103).
- Use of fans: with caution to ensure correct direction of flow; advise against ceiling fans.
- If placing plastic barriers, ensure that there is no interference with air flow.

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HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM

Summary

- SARS-CoV-2 is transmitted by fine aerosals containing virus that may remain suspended in the air
- Important to be prepared for the next surge of SARS-CoV2 or emergence of other respiratory tract pathogens
- In addition to masking (source control), spatial distancing, PPE (including respiratory protection), hand hygiene, vaccination, **optimizing ventilation systems** in facilities with vulnerable individuals is an important mitigation strategy
- Ventilation may be improved without a complete overhaul of the system

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HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM

Suggested Next Steps

- Invite CDPH Industrial Hygienists to provide a complete presentation of the details of ventilation
- Medical directors engage with facility infection preventionists and administrative directors to determine strategy for ventilation assessments
- Support ventilation assessments and consider recommendations together with the facility's leadership team

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Additional References

- www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Interim-Guidance-for-Ventilation-Filtration-and-Air-Quality-in-Indoor-Environments.aspx
- Laurent MR. Monitors to improve indoor air carbon dioxide concentrations in the hospital: A randomized crossover trial. doi.org/10.1016/j.scitotenv.2021.151349
- Zhu X. Nursing Home Design and COVID-19: Implications for Guidelines and Regulation. doi.org/10.1016/j.jamda.2021.12.026
- Lee.JH. Effectiveness of portable air filtration on reducing indoor aerosol transmission: preclinical observational trials. doi.org/10.1016/j.jhin.2021.09.012
- ASHRAE Core Recommendations for reducing airborne infectious aerosol exposure, 10/19/2021.
- Ventilation in Residential Care Facilities. U Nebraska.4.2021.

Questions?

Contact us:

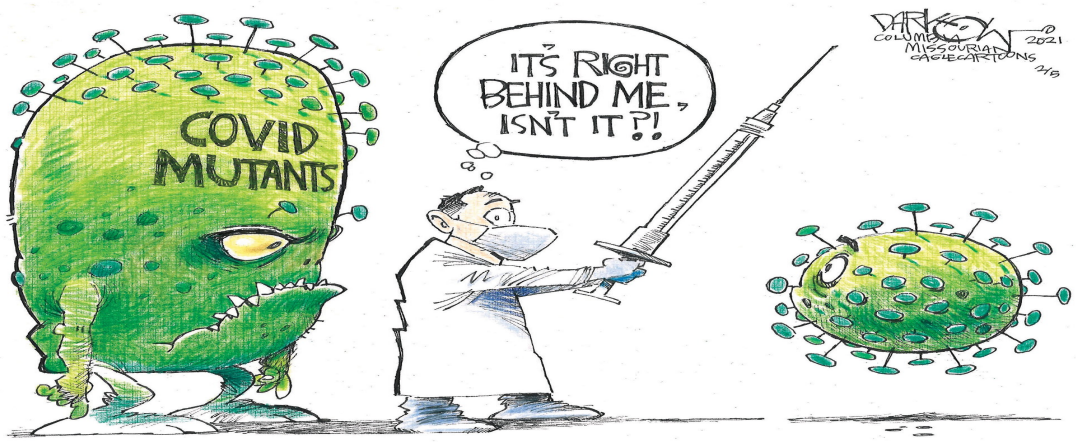
Jane.Siegel@cdph.ca.gov, HAI/Med epi

Kyle.Peerless@cdph.ca.gov, OHB/IH

Teresa.Nelson@cdph.ca.gov, HAI/IP

Second Booster

Ashkan Javaheri, MD, CMD



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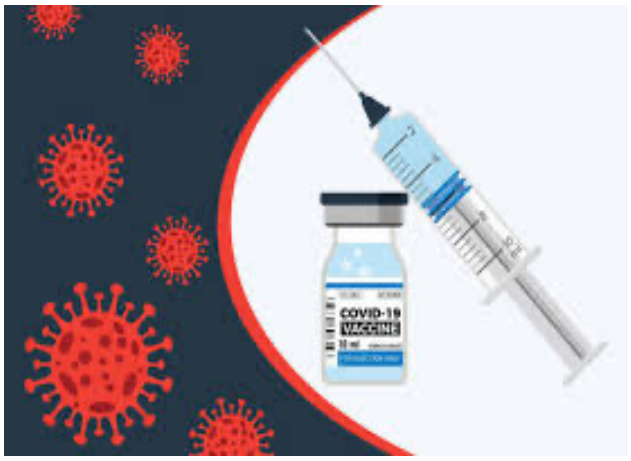
Objectives



- CDC recommendations on the second COVID-19 booster
- Discuss the available evidence

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Thinking About Getting a

Second COVID-19 Vaccine Booster Dose

In March 2022, CDC updated its COVID-19 vaccination guidance to say that certain groups of people *may* get second boosters. If you're in one of those groups, it's up to you whether or not to get a second booster right now, based on the benefits and risks the vaccine may provide to you. Your healthcare provider can help you review your options.
Here are factors to think about as you consider a second booster.

1. Are you eligible?	Right now, you're eligible for a 2nd COVID-19 booster if you're: - 50 years of age and older *and* received an initial booster at least 4 months ago. - 12 years of age and older *and* moderately or severely immunocompromised *and* received an initial booster at least 4 months ago - Received 2 doses of Janssen vaccine at least 4 months ago
2. Are you (or is someone you live with) more likely to get very sick?	Certain factors can make it more likely someone will get very sick from COVID-19. If you are eligible for a second booster (see above), it may be helpful to get a second booster now if you are (or if someone you live with is): - Moderately or severely immunocompromised - More likely to get very sick from COVID-19 - More likely to be exposed to COVID-19 through your job, where you live, or other factors (such as frequent travel or large gatherings) - In an area with medium to high COVID-19 community levels - Or if someone you live with is unvaccinated.
3. Can you wait?	Even if you are eligible for a second booster, you may consider waiting to get a second booster if you: - Had COVID-19 within the past 3 months - Feel that getting a second booster now would make you not want to get another booster in the future (a second booster may be more important in fall of 2022, or if a new vaccine for a future COVID-19 variant becomes available).
If you get a second booster:	- Make sure it's been at least 4 months since your last COVID-19 booster. - Remember that second boosters can only be Moderna or Pfizer-BioNTech (and for 12-17 year-olds, only Pfizer-BioNTech). - You can self-attest that you have a moderately or severely weakened immune system. This means you do not need any documentation that you have a weakened immune system to receive COVID-19 vaccines (including boosters) wherever they're offered.

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Effectiveness of a second BNT162b2 booster vaccine against hospitalization and death from COVID-19 in adults aged over 60 years

- Retrospective cohort study
- Aged 60 to 100 years
- A total of 563,465 participants
- 328,597 (58%) received a second-booster dose during the 40-day study period.
- **Hospitalizations** due to COVID-19 occurred in 270 of the second-booster recipients and in 550 participants who received one booster dose (**adjusted hazard ratio 0.36**; 95% confidence interval (CI): 0.31 to 0.43)
- **Death** due to COVID-19 occurred in 92 second-booster recipients and in 232 participants who received one booster dose (**adjusted hazard ratio 0.22**; 95% CI 0.17 to 0.28).

- Arbet et al, Nature April 2022

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Efficacy of a 4th Dose of COVID-19 mRNA Vaccine Against Omicron

- 1050 eligible health care workers
- 154 got 4th dose Pfizer-BioNTech
- 120 got 4th dose Monderna
- Matched controls

The NEW ENGLAND JOURNAL of MEDICINE

- Regev- Yochay, et al N Engl J Med 2022; 386:1377-1380

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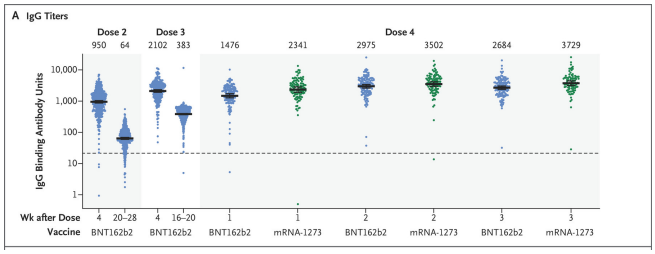
Efficacy of a 4th Dose of COVID-19 mRNA Vaccine Among Younger HC Workers

- IgG titers after three doses of BNT162b2 plus a fourth dose of a messenger RNA (mRNA) vaccine (either BNT162b2 or mRNA-1273).



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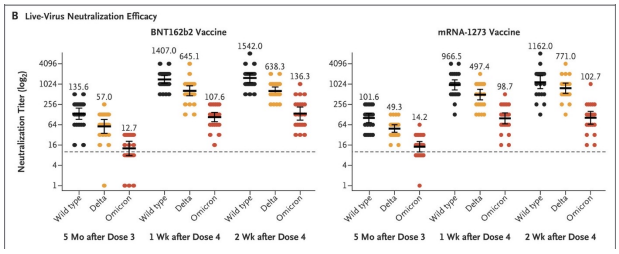
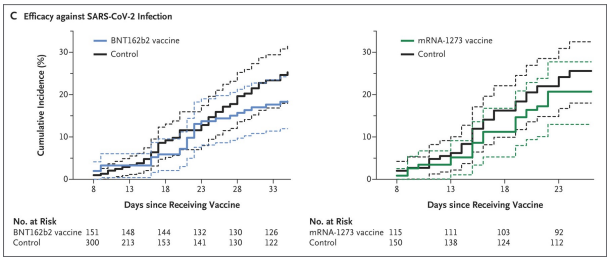
Efficacy of a 4th Dose of COVID-19 mRNAV

- Live-virus neutralization efficacy against different strains (Hu-1 [wild type], B.1.617.2 [delta], and B.1.1.529 [omicron]) at different time points.
- Geometric mean titers are shown, and I bars indicate the 95% confidence intervals; the dashed horizontal line indicates the cutoff for diagnostic positivity.



Efficacy of a 4th Dose of COVID-19 mRNA Vaccine Among Younger HC Workers

- The cumulative incidence of any severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection among BNT162b2 and mRNA-1273 recipients and their matched controls. The dashed lines indicate 95% confidence intervals.



Efficacy of a 4th Dose of COVID-19 mRNA Vaccine Among Younger HC Workers

- Infection rate
  - 25.0% of the participants in the control group were infected with the omicron variant
  - 18.3% of the participants in the BNT162b2 group
  - 20.7% of those in the mRNA-1273 group.
- Vaccine efficacy against any SARS-CoV-2 infection was
  - 30% (95% confidence interval [CI], −9 to 55) for BNT162b
  - 11% (95% CI, −43 to 44) for mRNA-1273
- Most infected health care workers reported negligible symptoms, both in the control group and the intervention groups.
- However, most of the infected participants were potentially infectious, with relatively high viral loads

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Efficacy of a 4th Dose of COVID-19 mRNA Vaccine Among Younger HC Workers

- The data provide evidence that a fourth dose of mRNA vaccine is immunogenic, safe, and somewhat efficacious
- The results suggest that maximal immunogenicity of mRNA vaccines is achieved after three doses and that antibody levels can be restored by a fourth dose
- Thus, a fourth vaccination of healthy young health care workers may have only marginal benefits.

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Waivers

Alex Bardakh, MPP, PLC
Director of Public Policy
AMDA-The Society for Post-Acute and Long-Term Care Medicine (AMDA)

May 2, 2022

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Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19

The Trump Administration is issuing an unprecedented array of temporary regulatory waivers and new rules to equip the American healthcare system with maximum flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic. Made possible by President Trump's recent emergency declaration and emergency rule making, these temporary changes will apply immediately across the entire U.S. healthcare system for the duration of the emergency declaration. The goals of these actions are to 1) to ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospital Without Walls); 2) remove barriers for physicians, nurses, and other clinicians to be readily hired from the community or from other states so the healthcare system can rapidly expands its workforce; 3) increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home; 4) expand in-place testing to allow for more testing at home or in community based settings; and 5) put Patients Over Paperwork to give temporary relief from many paperwork, reporting and audit requirements so providers, health care facilities, Medicare Advantage and Part D plans, and States can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19.

Medicare Telehealth

Clinicians can now provide more services to beneficiaries via telehealth so that clinicians can take care of their patients while mitigating the risk of the spread of the virus. Under the public health emergency, all beneficiaries across the country can receive Medicare telehealth and other communications technology-based services wherever they are located. Clinicians can provide these services to new or established patients. In addition, providers can waive Medicare copayments for these telehealth services for beneficiaries in Original Medicare.

To enable services to continue while lowering exposure risk, clinicians can now provide the following additional services by telehealth:

- Emergency Department Visits, Levels 1-5 (CPT codes 99281-99285)
- Initial and Subsequent Observation and Observation Discharge Day Management (CPT codes 99217- 99220; CPT codes 99224- 99226; CPT codes 99234- 99236)
- Initial hospital care and hospital discharge day management (CPT codes 99221-99223; CPT codes 99238- 99239)
- Initial nursing facility visits, All levels (Low, Moderate, and High Complexity) and nursing facility discharge day management (CPT codes 99304-99306; CPT codes 99315-99316)
- Critical Care Services (CPT codes 99291-99292)
- Domiciliary, Rest Home, or Custodial Care services, New and Established patients (CPT codes 99327- 99328; CPT codes 99334-99337)
- Home Visits, New and Established Patient, All levels (CPT codes 99341- 99345; CPT codes 99347- 99350)
- Inpatient Neonatal and Pediatric Critical Care, Initial and Subsequent (CPT codes 99468- 99473; CPT codes 99475- 99476)

- Initial and Continuing Intensive Care Services (CPT code 99477- 994780)
- Care Planning for Patients with Cognitive Impairment (CPT code 99483)
- Psychological and Neuropsychological Testing (CPT codes 96130- 96133; CPT codes 96136- 96139)
- Therapy Services, Physical and Occupational Therapy, All levels (CPT codes 97161- 97168; CPT codes 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521- 92524, 92507)
- Radiation Treatment Management Services (CPT codes 77427)
- Licensed clinical social worker services, clinical psychologist services, physical therapy services, occupational therapist services, and speech language pathology services can be paid for as Medicare telehealth services.

A complete list of all Medicare telehealth services can be found here:
https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes

Virtual Check-Ins & E-Visits

- Additionally, clinicians can provide virtual check-in services (HCPCS codes G2010, G2012) to both new and established patients. Virtual check-in services were previously limited to established patients.
- Licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, and speech language pathologists can provide e-visits. (HCPCS codes G2061-G2063).
- A broad range of clinicians, including physicians, can now provide certain services by telephone to their patients (CPT codes 98966 -98968; 99441-99443)

Remote Patient Monitoring

- Clinicians can provide remote patient monitoring services to both new and established patients. These services can be provided for both acute and chronic conditions and can now be provided for patients with only one disease. For example, remote patient monitoring can be used to monitor a patient's oxygen saturation levels using pulse oximetry. (CPT codes 99091, 99457-99458, 99473-99474, 99493-99494)

Removal of Frequency Limitations on Medicare Telehealth

To better serve the patient population that would otherwise not have access to clinically appropriate in-person treatment, the following services no longer have limitations on the number of times they can be provided by Medicare telehealth:

- A subsequent inpatient visit can be furnished via Medicare telehealth, without the limitation that the telehealth visit is once every three days (CPT codes 99231-99233);
- A subsequent skilled nursing facility visit can be furnished via Medicare telehealth, without the limitation that the telehealth visit is once every 30 days (CPT codes 99307-99310)
- Critical care consult codes may be furnished to a Medicare beneficiary by telehealth beyond the once per day limitation (CPT codes G0508-G0509).

Other Medicare Telehealth and Remote Patient Care

- For Medicare patients with End Stage Renal Disease (ESRD), clinicians no longer must have one "hands on" visit per month for the current required clinical examination of the vascular access site.
- For Medicare patients with ESRD, we are exercising enforcement discretion on the following requirement so that clinicians can provide this service via telehealth: individuals must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.
- To the extent that a National Coverage Determination (NCD) or Local Coverage Determination (LCD) would otherwise require a face-to-face visit for evaluations and assessments, clinicians would not have to meet those requirements during the public health emergency.
- Beneficiary consent should not interfere with the provision of telehealth services. Annual consent may be obtained at the same time, and not necessarily before, the time that services are furnished.
- Physician visits: CMS is waiving the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.

Workforce

- *Medicare Physician Supervision requirements:* For services requiring direct supervision by the physician or other practitioner, that physician supervision can be provided virtually using real-time audio/video technology.
- *Medicare Physician Supervision and Auxiliary Personnel:* The physician can enter into a contractual arrangement that meets the definition of auxiliary personnel at 42 CFR 410.26, including with staff of another provider/supplier type, such as a home health agency (defined under § 1861(o) of the Act) or a qualified home infusion therapy supplier (defined under § 1861(iii)(3)(D)), or entities that furnish ambulance services, that can provide the staff and technology necessary to provide care that would ordinarily be provided incident to a physicians' service (including services that are allowed to be performed via telehealth). In such instances, the provider/supplier would seek payment for any services provided by auxiliary personnel from the billing practitioner and would not submit claims to Medicare for such services.
- *Medicare Physician Supervision requirements:* Direct physician supervision is no longer required for non-surgical extended duration therapeutic services provided in hospital outpatient departments and critical access hospitals. Instead, a physician can provide a general level of supervision for these services so that a physician is no longer required to be immediately available in the office suite.
- *Physician Services:* CMS is waiving 482.12(c)(1-2) and (4), which requires that Medicare patients in the hospital be under the care of a physician. This allows hospitals to use other practitioners, such as physician's assistant and nurse practitioners, to the fullest extent possible. This waiver should be implemented in accordance with a state's emergency preparedness or pandemic plan.
- *National coverage determinations (NCDs) and Local Coverage Determinations (LCDs):* To the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish or supervise a service, during this public health emergency, the Chief Medical Officer or equivalent of a hospital or facility will have the authority to make those staffing decisions.

- *Practitioner Locations:* Temporarily waive Medicare and Medicaid's requirements that physicians and non-physician practitioners be licensed in the state where they are providing services. State requirements will still apply. CMS waives the Medicare requirement that a physician or non-physician practitioner must be licensed in the State in which s/he is practicing for individuals for whom the following four conditions are met: 1) must be enrolled as such in the Medicare program, 2) must possess a valid license to practice in the State which relates to his or her Medicare enrollment, 3) is furnishing services – whether in person or via telehealth – in a State in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity, and 4) is not affirmatively excluded from practice in the State or any other State that is part of the 1135 emergency area. A physician or non-physician practitioner may seek an 1135-based licensure waiver from CMS by contacting the provider enrollment hotline for the Medicare Administrative Contractor that services their geographic area. This waiver does not have the effect of waiving State or local licensure requirements or any requirement specified by the State or a local government as a condition for waiving its licensure requirements
- *Provider Enrollment:* CMS has established toll-free hotlines for physicians, non-physician practitioners and Part A certified providers and suppliers establishing isolation facilities to enroll and receive temporary Medicare billing privileges. CMS is providing the following flexibilities for provider enrollment:
  - Waive certain screening requirements.
  - Postpone all revalidation actions.
  - Allow licensed physicians and other practitioners to bill Medicare for services provided outside of their state of enrollment.
  - Expedite any pending or new applications from providers.
  - Allow practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from your currently enrolled location.
  - Allow opted-out practitioners to terminate their opt-out status early and enroll in Medicare to provide care to more patients.

Patients Over Paperwork

- *"Stark Law" Waivers:* The physician self-referral law (also known as the "Stark Law") prohibits a physician from making referrals for certain healthcare services payable by Medicare if the physician (or an immediate family member) has a financial relationship with the entity performing the service. There are statutory and regulatory exceptions, but in short, a physician cannot refer a patient to any entity with which he or she has a financial relationship. CMS will permit certain referrals and the submission of related claims that would otherwise violate the Stark Law. They include:
  - Hospitals and other health care providers can pay above or below fair market value to rent equipment or receive services from physicians (or vice versa). For example, a physician practice may be willing to rent or sell needed equipment to a hospital at a price that is below what the practice could charge another party. Or, a hospital may provide space on hospital grounds at no charge to a physician who is willing to treat patients who seek care at the hospital but are not appropriate for emergency department or inpatient care.
  - Health care providers can support each other financially to ensure continuity of health care operations. For example, a physician owner of a hospital may make a personal loan to the hospital without charging interest at a fair market rate so that the hospital can make payroll or pay its vendors.

- Hospitals can provide benefits to their medical staffs, such as multiple daily meals, laundry service to launder soiled personal clothing, or child care services while the physicians are at the hospital and engaging in activities that benefit the hospital and its patients.
- Allowing the provision of certain items and services that are solely related to COVID-19 Purposes (as defined in the waivers), even when the provision of the items or services would exceed the annual non-monetary compensation cap. For example, a home health agency may provide continuing medical education to physicians in the community on the latest care protocols for homebound patients with COVID-19, or a hospital may provide isolation shelter or meals to the family of a physician who was exposed to the novel coronavirus while working in the hospital's emergency department.
- Physician-owned hospitals can temporarily increase the number of their licensed beds, operating rooms, and procedure rooms, even though such expansion would otherwise be prohibited under the Stark Law. For example, a physician-owned hospital may temporarily convert observation beds to inpatient beds to accommodate patient surge during the COVID-19 pandemic in the United States.
- Loosen some of the restrictions when a group practice can furnish medically necessary designated health services (DHS) in a patient's home. For example, any physician in the group may order medically necessary DHS that is furnished to a patient by a technician or nurse in the patient's home contemporaneously with a physician service that is furnished via telehealth by the physician who ordered the DHS.
- Group practices can furnish medically necessary MRIs, CT scans or clinical laboratory services from locations like mobile vans in parking lots that the group practice rents on a part-time basis.

- *National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) on Respiratory Related Devices, Oxygen and Oxygen Equipment, Home Infusion Pumps and Home Anticoagulation Therapy:* Clinicians now have maximum flexibility in determining patient needs for respiratory related devices and equipment and the flexibility for more patients to manage their treatments at the home. The current NCDs and LCDs that restrict coverage of these devices and services to patients with certain clinical characteristics do not apply during the public health emergency. For example, Medicare will cover non-invasive ventilators, respiratory assist devices and continuous positive airway pressure devices based on the clinician's assessment of the patient.
- *Signature Requirements:* CMS is waiving signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment when a signature cannot be obtained because of the inability to collect signatures. Suppliers should document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19.
- *Changes to MIPS:* We are making two updates to the Merit-based Incentive Payment System (MIPS) in the Quality Payment Program. We are modifying the MIPS Extreme and Uncontrollable Circumstances policy to allow clinicians who have been adversely affected by the COVID-19 public health emergency to submit an application and request reweighting of the MIPS performance categories for the 2019 performance year. This is an important change that allows clinicians who have been impacted by the COVID-19 outbreak and may be unable to submit their MIPS data during the current submission period, to request reweighting and potentially receive a neutral MIPS payment adjustment for the 2021 payment year. Additionally, we are adding one new Improvement Activity for the CY 2020 performance year that, if selected, would provide high-weighted credit for clinicians within the MIPS Improvement Activities performance category. Clinicians will receive credit for this Improvement Activity by participating in a clinical trial utilizing a drug or biological product to treat a patient with COVID-19 and then reporting their findings to a clinical data repository or clinical data registry. This would help contribute to a clinicians overall MIPS final score, while providing important data to help treat patients and address the current COVID-19 pandemic.

- *Accelerated/Advance Payments:* In order to increase cash flow to providers impacted by COVID-19, CMS has expanded our current Accelerated and Advance Payment Program. An accelerated/advance payment is a payment intended to provide necessary funds when there is a disruption in claims submission and/or claims processing. CMS is authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider/supplier who submits a request to the appropriate Medicare Administrative Contractor (MAC) and meets the required qualifications. Each MAC will work to review requests and issue payments within seven calendar days of receiving the request. Traditionally repayment of these advance/accelerated payments begins at 90 days, however for the purposes of the COVID-19 pandemic, CMS has extended the repayment of these accelerated/advance payments to begin 120 days after the date of issuance of the payment. Providers can get more information on this process here: www.cms.gov/files/document/Accelerated-and-Advanced-Payments-Fact-Sheet.pdf.

Medicare appeals in Fee for Service, Medicare Advantage (MA) and Part D

- CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractor (QICs) in the FFS program 42 CFR 405.942 and 42 CFR 405.962 and MA and Part D plans, as well as the Part C and Part D Independent Review Entity (IREs), 42 CFR 562, 42 CFR 423.562, 42 CFR 422.582 and 42 CFR 423.582 to allow extensions to file an appeal;
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405. 950 and 42 CFR 405.966 and the Part C and Part D IREs to waive requirements for timeliness for requests for additional information to adjudicate appeals; MA plans may extend the timeframe to adjudicate organization determinations and reconsiderations for medical items and services (but not Part B drugs) by up to 14 calendar days if: the enrollee requests the extension; the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or, the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest 42 CFR § 422.568(b)(1)(i), § 422.572(b)(1) and § 422.590(f)(1);
- CMS is allowing MACs and QICs in the FFS program 42 C.F.R 405.910 and MA and Part D plans, as well as the Part C and Part D IREs to process an appeal even with incomplete Appointment of Representation forms 42 CFR § 422.561, 42 CFR § 423.560. However, any communications will only be sent to the beneficiary;
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405. 950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs to process requests for appeal that don't meet the required elements using information that is available 42 CFR § 422.562, 42 CFR § 423.562.
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405. 950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs, 42 CFR 422.562, 42 CFR 423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.

Additional Guidance

- The Interim Final Rule and waivers can be found at: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.
- CMS has released guidance to providers related to relaxed reporting requirements for quality reporting programs at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-15-NH & NLTC & LSC

DATE: **April 7, 2022**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Update to COVID-19 Emergency Declaration Blanket Waivers for Specific Providers

Memorandum Summary

- CMS continues to review the need for existing emergency blanket waivers issued in response to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- Over the course of the COVID-19 PHE, skilled nursing facilities/nursing facilities (SNFs/NFs), inpatient hospices, intermediate care facilities for individuals with intellectual disabilities (ICF/IIDs), and end-stage renal disease (ESRD) facilities have developed policies or other practices that we believe mitigates the need for certain waivers.
- Applicable waivers will remain in effect for hospitals and critical access hospitals (CAH).
- CMS will end the specified waivers in two groups:
    - 60 days from issuance of this memorandum
    - 30 days from issuance of this memorandum

Background

In response to the COVID-19 PHE and under the Secretary's authority set out at section 1135 of the Social Security Act, CMS enacted several temporary emergency declaration blanket waivers which were intended to provide health care providers with extra flexibilities required to respond to the COVID-19 pandemic.[1] CMS continues to evaluate the impact of these waivers on patient care and providers along with corresponding data.

While the waivers of regulatory requirements have provided flexibility in how nursing homes may operate, they have also removed the minimum standards for quality that help ensure residents' health and safety are protected. Findings from onsite surveys have revealed significant concerns with resident care that are unrelated to infection control (e.g., abuse, weight-loss, depression, pressure ulcers, etc.). We are concerned that the waiver of certain regulatory requirements has contributed to these outcomes and raises the risk of other issues. For example, by waiving requirements for training, nurse aides and paid feeding assistants may not have received the necessary training to help identify and prevent weight-loss. Similarly, CMS waived requirements for physicians and practitioners to perform in-person assessments, which may have

[1] COVID-19-emergency-declaration-waivers.pdf

prevented these individuals from performing an accurate assessment of the resident's clinical needs, contributing to depression or pressure ulcers. Lastly, due to the waiver of certain life-safety code requirements, facilities may not have had their fire prevention systems inspected to ensure they operate effectively to detect or prevent fire. As a result, CMS is very concerned about how residents' health and safety has been impacted by the regulations that have been waived, and the length of time for which they have been waived.

We note that CMS is still concerned about the risk COVID-19 poses to nursing home residents. We expect providers to continue to implement actions to reduce the likelihood of COVID-19 transmission and follow all existing requirements. For example, COVID-19 vaccines are the strongest tool we have to protect the health and safety of residents and staff, and facilities should use all available resources to support their residents and staff in getting vaccinated, and in doing so, adhere to the requirements for educating residents and staff regarding the benefits and potential side effects associated with the COVID-19 vaccine, and offering the vaccine (per Interim Final Rule CMS-3414-IFC).

However, in addition to taking actions to reduce the likelihood of the transmission of COVID-19, the minimum regulatory requirements need to be restored to protect residents' health and safety. This is particularly true in light of the increased protection against serious illness and death from COVID-19 afforded by the high and growing vaccination rates among nursing home residents and staff (see generally https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html), including as a result of the implementation and enforcement of Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,556 (Nov. 5, 2021). Therefore, we believe it is imperative that requirements to protect residents' health and safety be restored as soon as possible. The waivers listed below have been identified as those requirements that should be restored to address the risks to resident health and safety that are not related to infection control. Furthermore, we believe that at this time, nursing homes should be able to adjust their operations to meet these regulatory requirements, while also addressing any issues related to COVID-19. We note that states and individual facilities are still able to request regulatory waivers for issues unique to their facility or location (similar to actions taken in response to natural disasters) to provide flexibility.

Waiver Terminations:

CMS is ending the specific emergency declaration blanket waivers for SNFs/NFs, inpatient hospices, ICF/IIDs and ESRD facilities listed below. The termination of these blanket waivers will have no effect on other blanket waivers that remain in place such as those for hospitals and CAHs. Those blanket waivers remain in effect to assist hospitals and CAHs, among others, in dealing with their response to the surges of COVID-19 cases in the community. Providers are expected to take immediate steps so that they may return to compliance with the reinstated requirements according to the timeframes listed below. We also recommend that providers continue to follow CDC guidance for preventing the spread of COVID-19 especially during activities that may increase patient or resident contact. For additional information on individual waivers or flexibilities providers can apply for, please visit the Coronavirus waivers & flexibilities webpage.

Emergency Declaration Blanket Waivers Ending for SNF/NFs 30 Days from Publication of this Memorandum:

- Resident Groups - 42 CFR §483.10(f)(5)

    - CMS waived the requirements which ensure residents can participate in-person in resident groups. This waiver permitted the facility to restrict in-person meetings during the COVID-19 PHE.
- Physician Delegation of Tasks in SNFs - 42 CFR §483.30(e)(4)
    - CMS waived the requirement that prevents a physician from delegating a task when the regulations specify that the physician must perform it personally. This waiver gave physicians the ability to delegate any tasks to a physician assistant, nurse practitioner, or clinical nurse specialist, but specified that any task delegated under this waiver must continue to be under the supervision of the physician.
- Physician Visits - 42 CFR §483.30(c)(3)
    - CMS waived the requirement that all required physician visits (not already exempted in §483.30(c)(4) and (f)) must be made by the physician personally. The waiver modified this provision to permit physicians to delegate any required physician visit to a nurse practitioner, physician assistant, or clinical nurse specialist who is not an employee of the facility, who is working in collaboration with a physician, and who is licensed by the State and performing within the state's scope-of-practice laws.
- Physician Visits in Skilled Nursing Facilities/Nursing Facilities - 42 CFR §483.30
    - CMS waived the requirement for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.
- Quality Assurance and Performance Improvement (QAPI) – 42 CFR §483.75(b)–(d) and (e)(3)
    - CMS modified certain requirements which require long-term care facilities to develop, implement, evaluate, and maintain an effective, comprehensive, data-driven QAPI program. This waiver gave providers the ability to focus on adverse events and infection control, and those aspects of care delivery most closely associated with COVID-19 during the PHE.
- Detailed Information Sharing for Discharge Planning for Long-Term Care (LTC) Facilities - 42 CFR §483.21(c)(1)(viii)
    - CMS waived the discharge planning requirement which requires LTC facilities to assist residents and their representatives in selecting a post-acute care provider using data, such as standardized patient assessment data, quality measures and resource use. CMS maintained all other discharge planning requirements.
- Clinical Records - 42 CFR §483.10(g)(2)(ii)
    - CMS modified the requirement which requires long-term care (LTC) facilities to provide a resident a copy of their records within two working days (when requested by the resident).

Emergency Declaration Blanket Waivers For Various Provider-Types Ending <u>60 Days</u> from Publication of this Memorandum:

- Physical Environment for SNF/NFs - 42 CFR §483.90
    - CMS waived requirements to allow for a non-SNF building to be temporarily certified and available for use by a SNF in the event there were needs for isolation processes for COVID-19 positive residents, which may not be feasible in the existing SNF structure to ensure care and services during treatment for COVID-19, provided that the state has approved the location as one that sufficiently addresses safety and comfort for patients and staff.

    - Certain conditions of participation and certification requirements for opening a NF if the state determines there is a need to quickly stand up a temporary COVID-19 isolation and treatment location.
    - Requirements to temporarily allow for rooms in a long-term care facility not normally used as a resident's room, to be used to accommodate beds and residents for resident care in emergencies and situations needed to help with surge capacity.
- Equipment Maintenance & Fire Safety Inspections for ESRD facilities - 42 CFR §494.60(b) and(d)
    - CMS waived the requirement for on-time preventive maintenance of dialysis machines and ancillary dialysis equipment. Additionally, CMS waived the requirements for ESRD facilities to conduct on-time fire inspections.
- Facility and Medical Equipment Inspection, Testing & Maintenance (ITM) for Inpatient Hospice, ICF/IIDs and SNFs/NFs – 42 CFR §§418.110(c)(2)(iv), 483.470(j), and 483.90
    - CMS waived ITM requirements for facility and medical equipment to reduce disruption of patient care and potential exposure/transmission of COVID-19.
- Life Safety Code (LSC) and Health Care Facilities Code (HCFC) ITM for Inpatient Hospice, ICF/IIDs and SNFs/NFs - 42 CFR §§ 418.110(d)(1)(i) and (e), 483.470(j)(1)(i) and (5)(v), and 483.90(a)(1)(i) and (b)
    - CMS waived ITM required by the LSC and HCFC, with specified exceptions, which permitted facilities to adjust scheduled ITM frequencies and activities to the extent necessary.
- Outside Windows and Doors for Inpatient Hospice, ICF/IIDs and SFNs/NFs – 42 CFR §§418.110(d)(6), 483.470(e)(1)(i), and 483.90(a)(7)
    - CMS waived the requirement to have an outside window or outside door in every sleeping room. This permitted spaces not normally used for patient care to be utilized for patient care and quarantine.
- Life Safety Code for Inpatient Hospice, ICF/IIDs, and SNFs/NFs - 42 CFR §§418.110(d), 483.470(j), and 483.90(a)
    - CMS waived these specific LSC provisions:
        - Fire Drills: Due to the inadvisability of quarterly fire drills that move and mass staff together, CMS permitted a documented orientation training program related to the current fire plan, which considered current facility conditions.
        - Temporary Construction: CMS waived requirements that would otherwise not permit temporary walls and barriers between patients.
- Paid Feeding Assistants for LTC facilities: 42 CFR §§483.60(h)(1)(i) and 483.160(a)
    - CMS modified the requirements regarding required training of paid feeding assistants to allow that training can be a minimum of one hour in length. CMS did not waive other requirements related to paid feeding assistants or required training content.
- In-Service Training for LTC facilities – 42 CFR §483.95(g)(1)
    - CMS modified the nurse aide training requirements for SNFs and NFs, which required the nursing assistant to receive at least 12 hours of in-service training annually.
- Training and Certification of Nurse Aides for SNF/NFs - 42 CFR §483.35(d) (Modification and Conditional Termination)
    - CMS waived the requirements which require that a SNF and NF may not employ anyone for longer than four months unless they met the training and certification requirements under §483.35(d). CMS previously provided information related to

nurse aides working under this blanket waiver in CMS memorandum QSO-21-17-NH. This memo provides additional information as well on the modification of this waiver below.

We remind states that all nurse aides, including those hired under the above blanket waiver at 42 CFR §483.35(d), must complete a state approved Nurse Aide Competency Evaluation Program (NATCEP) to become a certified nurse aide. State approved NATCEPs must have a curriculum that includes training in the areas defined at 42 CFR §483.152(b), such as respecting residents' rights, basic nursing skills, personal care skills, and caring of cognitively impaired residents. Additionally, the requirements at 42 CFR §483.154(b)(i) and (ii) requires these nurse aides pass a written or oral exam, and demonstrate skills learned. Lastly, we note that CMS did not waive the requirement that the individual employed as a nurse aide be competent to provide nursing and nursing related services at 42 CFR §483.35(d)(1)(i), and that requirement must continue to be met.

We are aware that there may be instances where the volume of aides that must complete a state approved NATCEP exceed the available capacity for enrollees in a training program or taking the exam. This may cause delays in in nurse aides becoming certified. If a facility or nurse aide has documentation that demonstrates their attempts to complete their training and testing (e.g., timely contacts to state officials, multiple attempts to enroll in a program or test), a waiver of these requirements (42 CFR §483.35(d)) is still available and the aide may continue to work in the facility while continuing to attempt to become certified as soon as possible. However, **for all other situations, this waiver is terminated**. When capacity issues exist, facilities should inform their state officials of the issue. State agencies should also verify the capacity issues that are reported. Lastly, state agencies should provide their CMS Location with information about the status of their NATCEPs.

Poor quality of care, such as improper transfers, turning and positioning, poor incontinent/skin care, or weight loss related to poor assistive dining techniques could be related to inadequate training, as these skills are required components of NATCEP programs. We acknowledge that federal requirements allow states to use a variety of means to administer the curriculum (e.g., online, classroom, or onsite training). However, all programs must adequately provide the required training. For example, if a state has approved a NATCEP that allows for the time worked onsite by a nurse aide over the COVID-19 PHE to qualify for the 75 hours training in the required areas, yet, observes trends in poor quality of care among certified nurse aides that were hired under the nurse aide training waiver, this could indicate that the NATCEP does not adequately address the components of the required curriculum specified at 42 CFR §483.152(b). In these cases, the state should re-evaluate the approved NATCEP to see if the components of the program need to be adjusted to ensure the regulatory requirements are met and avoid poor quality of care. As stated in CMS memorandum QSO-21-17-NH, "states must ensure that all of the required areas of training per 42 CFR §483.152(b) are addressed, and any gaps in onsite training that are identified are fulfilled through supplemental training."

Contact:
DNH_TriageTeam@cms.hhs.gov for questions related to nursing homes;
QSOG_LifeSafetyCode@cms.hhs.gov for questions related to physical environment and life safety code.

Effective Date: The emergency declaration blanket waivers identified above will end according to the timeframes described in this memorandum.

/s/
David R. Wright

cc: Survey and Operations Group Management

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

News Flash –

CMS has instructed its contractors to delay turning on Phase 2 denial edits on the following claims to check for a valid individual National Provider Identifier (NPI) and to deny the claim when this information is missing:

- Medicare Part B **laboratory and imaging** claims and Durable Medical Equipment, Orthotics, and Supplies (DMEPOS) claims that require an ordering or referring physician/non-physician provider; and
- Part A Home Health Agency (HHA) claims that require an attending physician provider.

CMS will advise you of the new implementation date in the near future. In the interim, informational messages will continue to be sent for those claims that would have been denied had the edits been in place. See **MLN Matters® Article SE1305** for more information.

MLN Matters® Number: SE1308 Revised

Related Change Request (CR) #: NA

Related CR Release Date: NA

Effective Date: March 8, 2013

Related CR Transmittal #: NA

Implementation Date: March 8, 2013

Physician Delegation of Tasks in Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs)

Note: This article was revised on April 30, 2013, to revise the news flash (above) to show the Phase 2 edits are delayed. All other information remains the same.

Provider Types Affected

This MLN Matters® Article Special Edition (SE) is intended for physicians, non-physician practitioners (NPPs) and providers who bill for services related to beneficiaries in Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs).

Provider Action Needed

The Centers for Medicare & Medicaid Services (CMS) is publishing this article to provide clarification of Federal guidance regarding Section 3108 of the Affordable Care Act (ACA), related to physician delegation of certain tasks in SNFs and NFs to NPPs (NPPs are formerly "physician extenders") such as nurse practitioners (NPs), physician assistants (PAs), or clinical nurse specialists (CNSs).

This article addresses the authority of NPs, PAs, or CNSs to perform certain tasks such as conducting physician visits and writing orders, and to sign certifications and re-certifications.

Background

CMS is clarifying the regulatory differences concerning physician delegation of tasks in SNFs and NFs. The distinction in policies between these two settings (SNFs and NFs) is based in statute and regulation. Improper application of these regulations may affect a facility's compliance and payment to providers.

The key to accurate application is to identify:

1. In which setting, SNF or NF, the physician services are being provided;
2. Whether the task must be performed personally by the physician; and
3. Whether or not the NPP is employed by the facility.

The "setting" is determined by whether the visit to a patient in a certified bed is:

1. To a resident whose care is paid for by Medicare Part A in a SNF; or
2. To a resident whose care is paid for by Medicaid in a NF.

Key Points

The requirements for long-term care facilities, specified in 42 CFR section 483.40(e)(2), provide that, "A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies." The following bullets outline when and which tasks may be delegated:

Physician Required and other Medically Necessary Visits during a SNF Stay:

- A required physician visit includes the initial comprehensive visit in a SNF and every alternate required visit thereafter. (See 42 CFR 483.40(c)(4).) The initial comprehensive visit in a SNF is the initial visit during which:
    - The physician completes a thorough assessment; and
    - Develops a plan of care and writes or verifies admitting orders for the resident.

- The initial comprehensive visit must occur no later than 30 days after a resident's admission into the SNF. The physician may not delegate the initial comprehensive visit in a SNF.
- NPPs may perform other medically necessary visits prior to and after the physician's initial comprehensive visit.
- Once the physician has completed the initial comprehensive visit in the SNF, the physician may then delegate alternate visits to a PA, NP, or CNS who is licensed as such by the State and performing within the scope of practice in that State. These alternate visits, as well as medically necessary visits, may be performed and signed by the NPP (physician co-signature is not required).

Certifications/Re-certifications in SNFs:

- 42 CFR 424.20(e)(2) (which reflects the requirements of section 1814 (a)(2) of the Social Security Act (Act)) states that NPs and CNSs who are not employed by the facility and who are working in collaboration with a physician may sign the required initial certification and re-certifications of a beneficiary's need for SNF level of care.
- Effective with services furnished on or after January 1, 2011, physician assistants who are not employed by the facility are authorized to perform the required initial certification and periodic re-certifications of a beneficiary's need for a SNF level of care.

Performance of Physician Tasks in NFs:

- Similar to a SNF, the initial comprehensive visit in a NF is the initial visit during which:
  - The physician completes a thorough assessment; and
  - Develops a plan of care and writes or verifies admitting orders for the resident.
- The initial comprehensive visit must occur no later than 30 days after admission.

Note: At the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a NP, CNS, or PA who is not an employee of the facility but who is working in collaboration with a physician.

In other words, NPPs that have a direct relationship with a physician and who are not employed by the facility may perform the initial comprehensive visit, any other required physician visit, and other medically necessary visits for a resident of a NF as the State allows. NPPs may also perform other medically necessary visits prior to and after the physician initial comprehensive visit.

Medically necessary visits performed by NPs, CNSs, and PAs employed by the facility may not take the place of the physician required visits, nor may the visit count towards meeting the required physician visit schedule prescribed at 42 CFR 483.40(c)(1). However:

- At the option of the State, NPs, PAs, and CNSs who are employees of the facility, while not permitted to perform visits required under the schedule prescribed at 42 CFR 483.40(c)(1),

are permitted to perform other medically necessary visits and write orders based on these visits.

- For example, if a resident complains of a headache, the NP, CNS, or PA employed by the NF may assess the resident and write orders to address the condition;
- The physician is not required, other than by State law as applicable, to verify and sign orders written by NPPs who are employed by the facility for other medically necessary visits; and
- These medically necessary visits performed by NPs, CNSs, and PAs employed by the facility may not take the place of the physician required visits, nor may the visit count towards meeting the required physician visit schedule prescribed at 42 CFR 483.40(c)(1).

NPs, PAs and CNSs must collaborate with a physician:

- In contrast to the initial SNF visit, NPPs may provide initial NF visits and other required visits under 42 CFR 483.40(c)(3) and (f) if the State permits it;
- Required physician tasks, such as verifying and signing orders in an NF, may be delegated to a PA, NP, or CNS who is **not** an employee of the facility, but who is working in collaboration with a physician; and
- Orders written by an NPP who is employed by the NF and are written during visits that are not required visits, and are therefore "other medically necessary visits," do not require physician co-signature except as mandated by State law.

CMS is issuing this clarification because, where a NPP is permitted to perform a medically necessary visit, the NPP is likewise permitted to write applicable orders during that visit. The Federal requirements restricting NPPs who are employed by the NF from performing a required visit, do not apply to other medically necessary visits. Thus, this guidance clarifies when an NPP employed by a NF may write orders without a countersignature unless State law requires it.

Note: The following regulatory language is included for reference purposes:

Section 483.40(f) Performance of Physician Tasks in NFs: At the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.

Dually-Certified Facilities (SNF/NFs)

In a facility where beds are dually–certified under Medicare and Medicaid, the facility must determine how the particular resident stay is being paid.

- For residents in a Part A Medicare stay, the NPP must follow the guidelines for services in a SNF.
- For residents in a Medicaid stay, the NPP must follow the provisions outlined for care in NFs.
- In a dually-certified nursing home, any required physician task for a Medicaid beneficiary in a Medicaid stay, at the option of the State, may be performed by a NPP who is not an employee of the facility but who is working in collaboration with a physician.
- In a dually-certified nursing home and at the option of a physician, required physician visits for a Medicare beneficiary in a Part A Medicare stay may be alternated between personal visits by the physician and visits by a NPP after the physician makes the initial first visit.

The following table summarizes the requirements for NPPs to perform visits, sign orders, and sign certifications and re-certifications, when this function is permitted under the scope of practice for the State.

Authority for NPPs to Perform Visits, Sign Orders and Sign Certifications/Re-certifications When Permitted by the State*

	Initial Comprehensive Visit /Orders	Other Required Visits^	Other Medically Necessary Visits & Orders+	Certification/ Recertification
SNFs				
PA, NP & CNS employed by the facility	May not perform/ May not sign	May perform alternate visits	May perform and sign	May not sign
PA, NP & CNS not a facility employee	May not perform/ May not sign	May perform alternate visits	May perform and sign	May sign subject to State requirements
NFs				
PA, NP & CNS employed by the facility	May not perform/ May not sign	May not perform	May perform and sign	Not applicable ±
PA, NP & CNS not a facility employee	May perform/ May sign	May perform	May perform and sign	Not applicable ±

*This reflects clinical practice guidelines
^Other required visits are the required monthly visits.
+Medically necessary visits may be performed prior to the initial comprehensive visit.
± This requirement relates specifically to coverage of a Part A Medicare stay, which can take place only in a Medicare-certified SNF.

Additional Information

To review 42 CFR 483.40, go to http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol5/pdf/CFR-2011-title42-vol5-sec483-40.pdf on the Internet.

To review 42 CFR 424.20 go **to** http://www.gpo.gov/fdsys/pkg/CFR-2009-title42-vol3/pdf/CFR-2009-title42-vol3-sec424-20.pdf on the Internet.

To review the memorandum that is the basis for this article and discusses physician delegation of tasks in SNFs and NFs go to http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-15-.pdf on the CMS website.

To review the Section 3108 of the Affordable Care Act (page 300), Permitting Physician Assistants To Order Post-Hospital Extended Care Services, go to:http://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf on the Internet

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