

COVID-19 Vaccination Mandate

Management of Requests for Medical Exemptions

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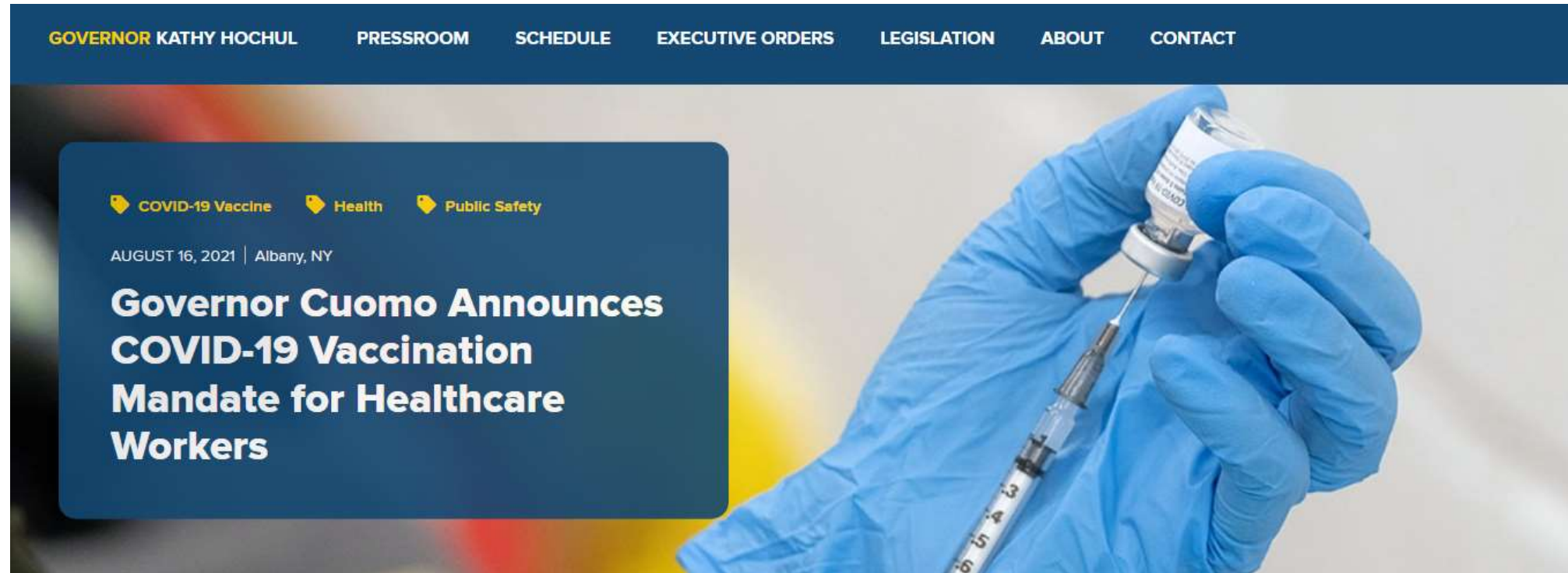


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Agenda

1. Background/Context
 - A. State Mandates
 - B. Medical Accommodation
2. COVID-19 Vaccination Medical Exemption & Review Process
3. Outcomes
4. Learning points
5. Discussion/Q&A

New York State Mandate for COVID-19 Vaccination in Healthcare Workers



Department of Health Issues Section 16 Orders to Hospitals and Long-Term Care Facilities Requiring Policy to Ensure All Employees Are Vaccinated

First Dose Required by September 27

New Jersey State Mandate for COVID-19 Vaccination Booster in Healthcare Workers



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Governor Murphy Signs Executive Order Clarifying COVID-19 Vaccine Requirements for Workers in Health Care and Congregate Settings

04/13/2022

TRENTON – Governor Phil Murphy today signed Executive Order No. 294, clarifying that vaccination requirements for covered workers at health care and high-risk congregate settings under Executive Order No. 283 include only one booster dose of the COVID-19 vaccine and that a second booster dose is not required. A covered worker is considered “up to date with their COVID-19 vaccinations” if they have received a primary series, which consists of either a 2-dose series of an mRNA COVID-19 vaccine or a single dose COVID-19 vaccine and the first booster dose for which they are eligible, as recommended by the Centers for Disease Control and Prevention.

“Even though it is not required, I encourage New Jerseyans who the CDC has advised would benefit from their second booster to roll up their sleeves and give themselves an added dose of defense against COVID-19, like I did yesterday,” said Governor Murphy. “The numbers here in New Jersey and from around the nation are clear – getting boosted is directly linked to less-severe COVID-19 symptoms and illness and far lower rates of hospitalization and death. Our steadfast vaccination efforts have effectively lowered the risk we face in New Jersey, and as we navigate the path to normalcy, we must continue to do all we can to protect ourselves, our families, and our communities.”

Covered health care settings and covered high-risk congregate settings must maintain a policy pursuant to Executive Order No. 283 that requires covered workers to provide adequate proof that they are up to date with their COVID-19 vaccinations.

Workplace Accommodation and the COVID-19 Vaccination Mandate for HCP



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Workplace Accommodation

A **workplace accommodation** refers to reasonable changes made by an employer to an employee's job duties or work environment that make it possible for an employee with a disability, pregnancy, religious practice, or status as a victim of domestic violence, sex offenses, or stalking to perform the essential functions of the job. Disability includes a physical or mental impairment or medical condition that substantially limits a major life activity.

Under the Americans with Disabilities Act (ADA) and the New York City Human Rights Law, employers are required to provide reasonable accommodations to qualified employees in these situations unless doing so would pose an undue hardship on the employer.

[Request a Workplace Accommodation](#)

Forms

 [Accommodation Agreement](#)

Review: Reasons to make medical accommodations

It's the right thing to do

- Support employees
- Retain experienced workforce
- Regulatory and compliance
 - ✓ ADA, EEOC
 - ✓ state and local accommodation laws
 - ✓ state mandates for vaccination of healthcare worker
 - ✓ Organizational policies (e.g. IC, HR, Occ Health)

Medical Exemption from COVID-19 Vaccination

- Designed and Implemented procedure to review and document hundreds of requests from employees
- Ensured consistent, ADA compliant interactive process
- Enlisted participation of key stakeholders and experts (e.g. Employee Health, HR, Legal, Regulatory Affairs, Various Specialists, Ethics)
- Delivered timely responses to requests for metrics and reports to Executive Leadership and others
- As of 1/13/2023: 364 requests handled, with 16 permanent exemptions for initial vaccine series and 14 exemptions for vaccine booster (NJ) in place at MSK

Source: Cority

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COVID-19 Vaccine Medical Exemption Request and Review Process

- Anyone requesting a medical exemption must access, complete, and email the **Request for Medical Exemption from COVID-19 Vaccination Form** to COVIDEXEMPT@mskcc.org
- The medical exemption request form must be signed by a medical provider (physician or APP) confirming the basis for the request. The requester must sign the medical exemption request form authorizing MSK to contact the requester's health care provider or specialist to discuss any medical condition and request and obtain any medical record associated with this request as needed.
- The requester must also submit the signed medical release or HIPAA Form.
- Submitted documents are reviewed for completeness by Employee Health staff, ensuring they are signed by a licensed practitioner with credentials for the appropriate specialty for the condition for which the exemption is requested.
- Employees are notified if their documents are incomplete and informed of what is missing.

COVID-19 Vaccine Medical Exemption Request and Review Process

- The COVID-19 Vaccination Medical Exemption Review Committee (Committee) reviews complete requests considering recognized clinical contraindications or applicable federal laws.
- The Committee may contact the requester for a conversation and may require additional information from the employee's personal medical provider and/or specialist, to supplement the written information provided, as needed. (Interactive process and cooperative dialogue)
- Review may take up to two weeks.

COVID-19 Vaccine Medical Exemption Request and Review Process

- Requests for medical exemptions are considered individually.
- Privacy and fairness are maintained throughout process.
- Committee review meetings were scheduled 3-5 times a week in advance of state mandates and are currently scheduled on an as needed basis.
- Committee consists of specialists and experts, including, but not limited to internal medicine, allergy and immunology, cardiology, critical care, OB/GYN, pediatrics, rheumatology, pharmacy, infectious disease, ethics, and legal & regulatory affairs.
- Committee consults with other specialties as needed.
- Approval or denial of the exemption request is done by consensus of the committee.
- The Committee's determination is emailed to the requester and their manager. Emails communicating the committee's decision are saved in the employee's health record in Cority.

Establish rapport as a trusted clinician

Interactive Process for Vaccine Medical Exemption Requests

1. Always approach the employee with an attitude of empathy and understanding, ensuring that the employee feels heard and respected throughout the process.
2. A conversation (face to face, virtual, or by phone) is preferred over an email for establishing a trusting rapport.
3. Avoid language or questioning that may make the employee feel doubted or invalidated.
4. It's clinician's responsibility to evaluate the *medical* reason for the exemption request.



**Learning
points**

For concerns expressed about fairness of review process or the vaccine mandate

Interactive Process for Vaccine Medical Exemption Requests

1. Design the Medical Exemption Request Form in anticipation of the need to contact providers for more information,
 - Sample language: “I acknowledge that this Request for Medical Exemption authorizes XXX Medical Center to contact the below-designated health care provider to discuss any medical condition associated with this request and obtain any relevant medical records and I consent to all such contact for this purpose.”
2. Proactively consider how your process will be thorough, fair and consistent
 - Maintain confidentiality and anonymity of the requesting employee. Cases are reviewed by using case numbers and decisions are made by consensus of the Committee.
3. Identify partners who will provide support for non-medical questions from staff (e.g. questions about fairness of mandates, questions about disciplinary action, etc.)

Interactive Process for Vaccine Medical Exemption Requests

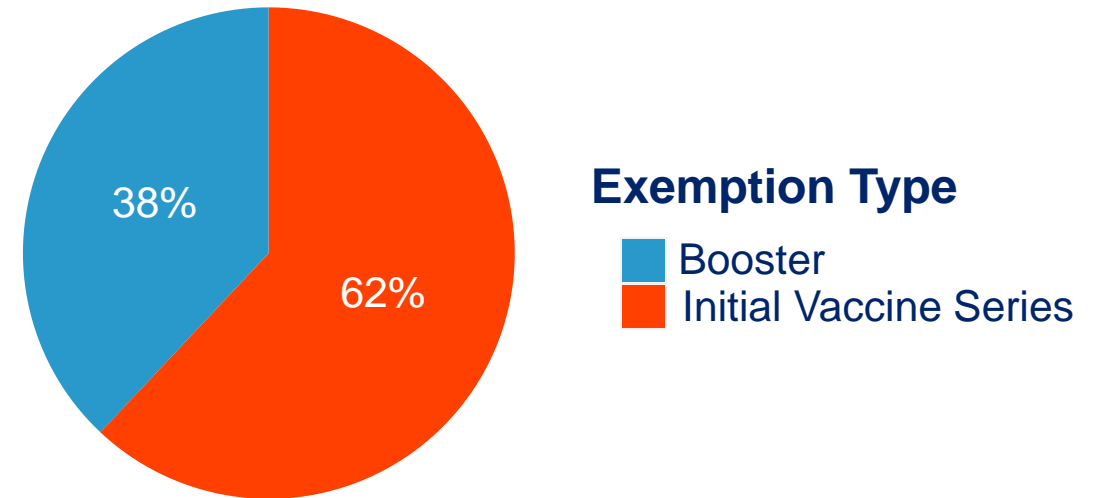
- If the conversation becomes contentious, let the individual know that their concerns are important, and that you would like to get back to them after looking into it further.
- Anticipate questions and create resources
For example, “For additional medical exemption related questions, please see the XXX page which includes FAQs at <https://mskcc.sharepoint.com/sites/pub-XXX>”

Completed COVID-19 Medical Exemption Requests

Source: Cority

Date data was pulled: 12/19/2022

Exemption Type	Count
Initial Vaccine Series	214
Booster	131
Total	345



*Employees with 100% remote exemptions were removed from the data

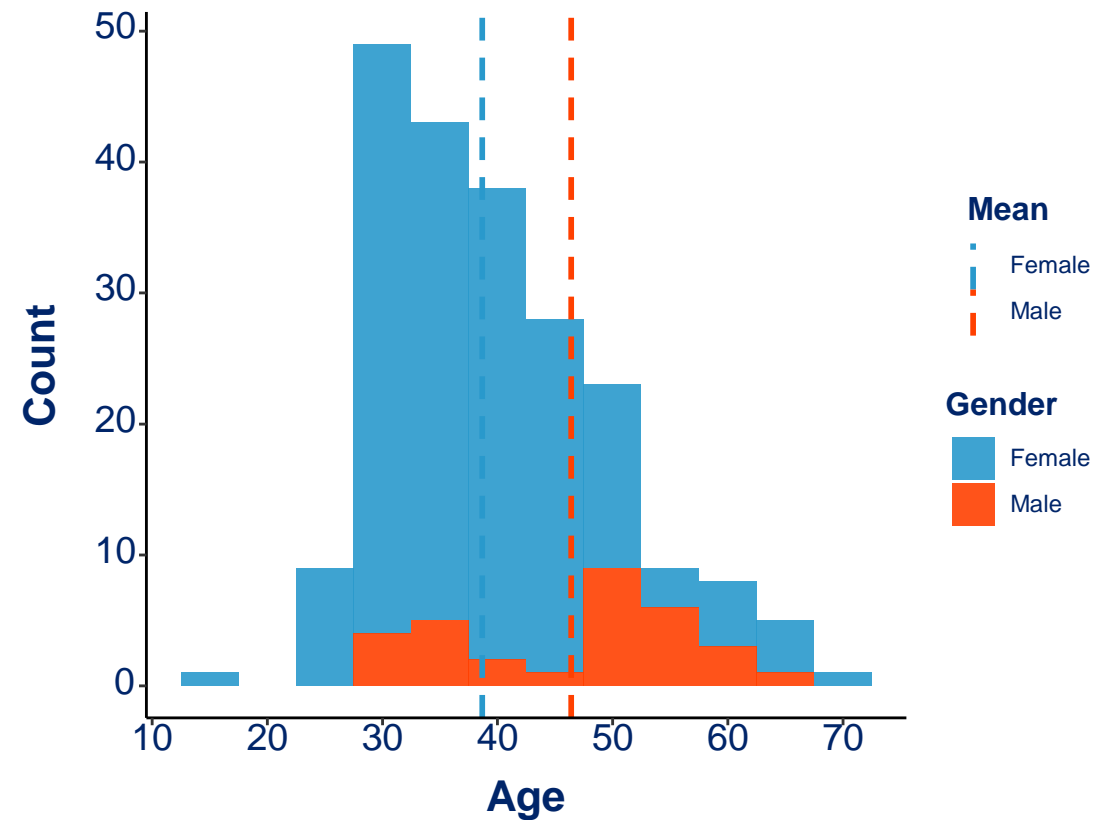
COVID-19 Initial Vaccine Series Medical Exemptions Requests Analysis (Includes Pregnancy & Fertility)

Gender	Mode	Mean	Median	Min	Max
Female	32	39	37	17	68
Male	49	46	49	28	63

Notes:

- Bimodal distribution for males, two peaks (30-40 & 50-60 range)
- Larger population of females for exemptions
- MSK population:
 - 65% female, 34% male, 1% preferred not to disclose
 - Mean age: 39 female, 41 male
 - More requests from the younger female population
 - Median: 36 female, 38 male

Histogram of Age by Gender



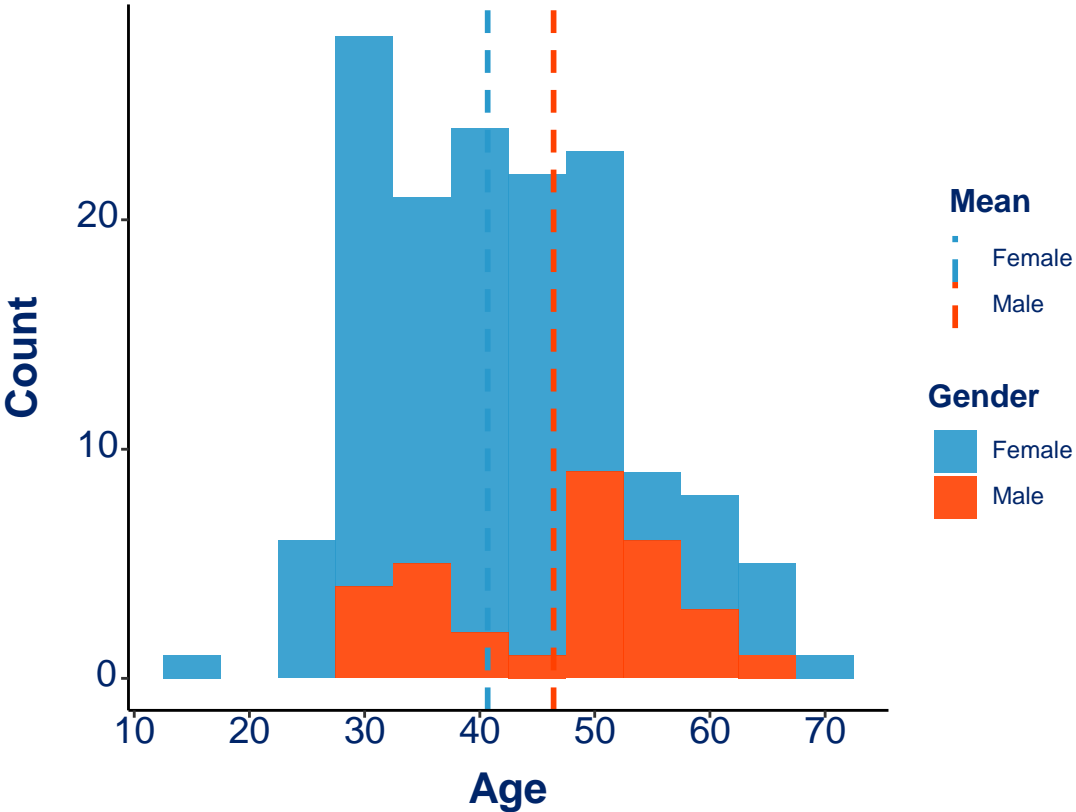
COVID-19 Initial Vaccine Series Medical Exemptions Requests Analysis (Excludes Pregnancy and Fertility Treatments)

Gender	Mode	Mean	Median	Min	Max
Female	28	41	40	17	68
Male	49	46	49	28	63

Notes:

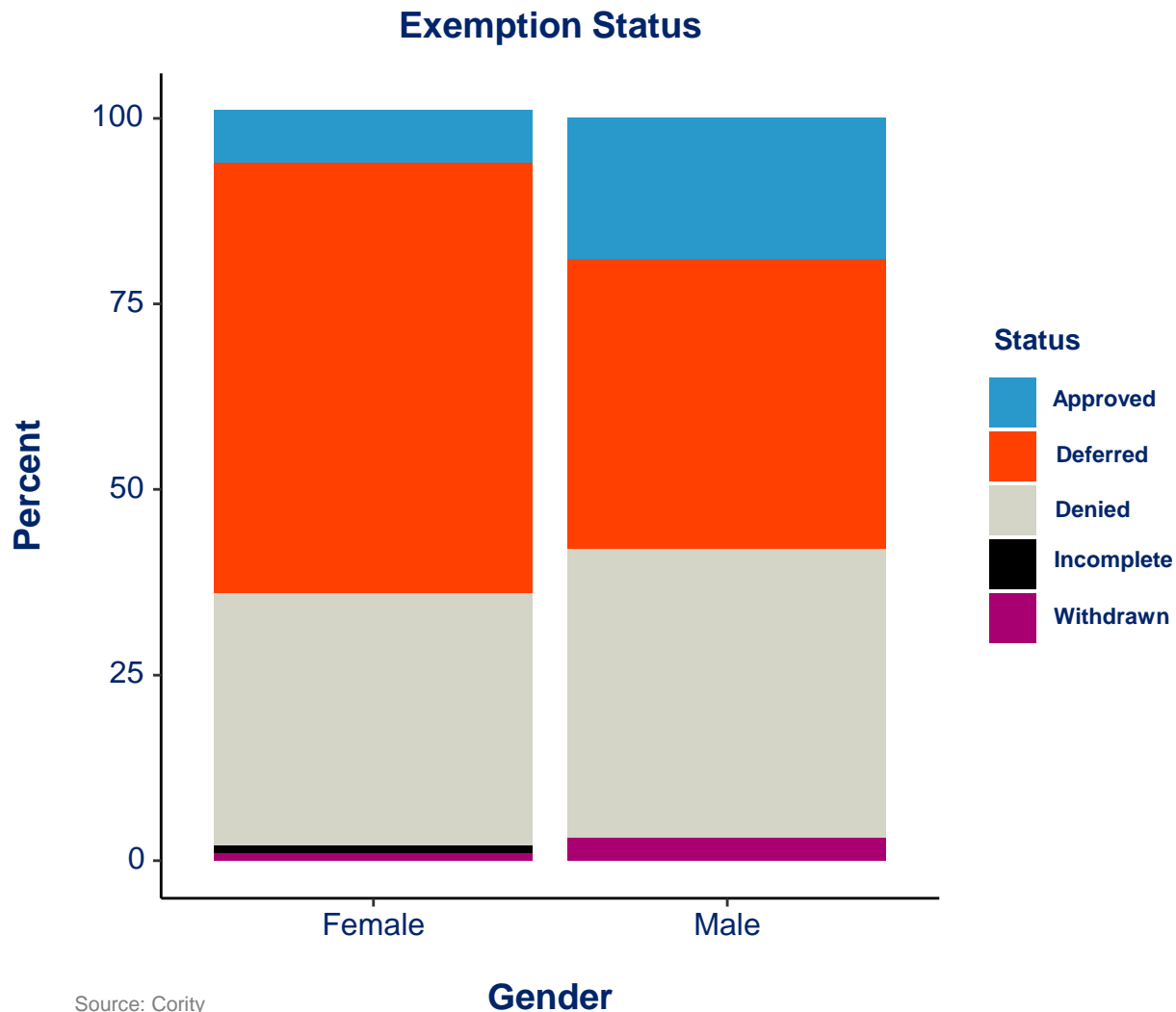
- Does not include pregnancy and fertility treatments within the data.
 - Mode 28 (w/o fertility & pregnancy) vs 32 (w/ fertility and pregnancy)
 - Mean 41 vs 39, Median 40 vs 37
- There is still a larger population of females for exemptions
- MSK population:
 - 65% female, 34% male, 1% preferred not to disclose
 - Mean age: 39 female, 41 male, 39 preferred not to disclose
 - More requests from the younger female population
 - Median: 36 female, 38 male, 35 preferred not to disclose

Histogram of Age by Gender



Source: Cority
 Date data was pulled: 12/19/2022
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Medical Exemption Status for Initial Vaccine Series



Status	Female	Male	Total
Deferred	106	12	118
Denied	62	12	74
Approved	12	6	18
Incomplete	2	0	2
Withdrawn	1	1	2
Grand Total	183	31	214

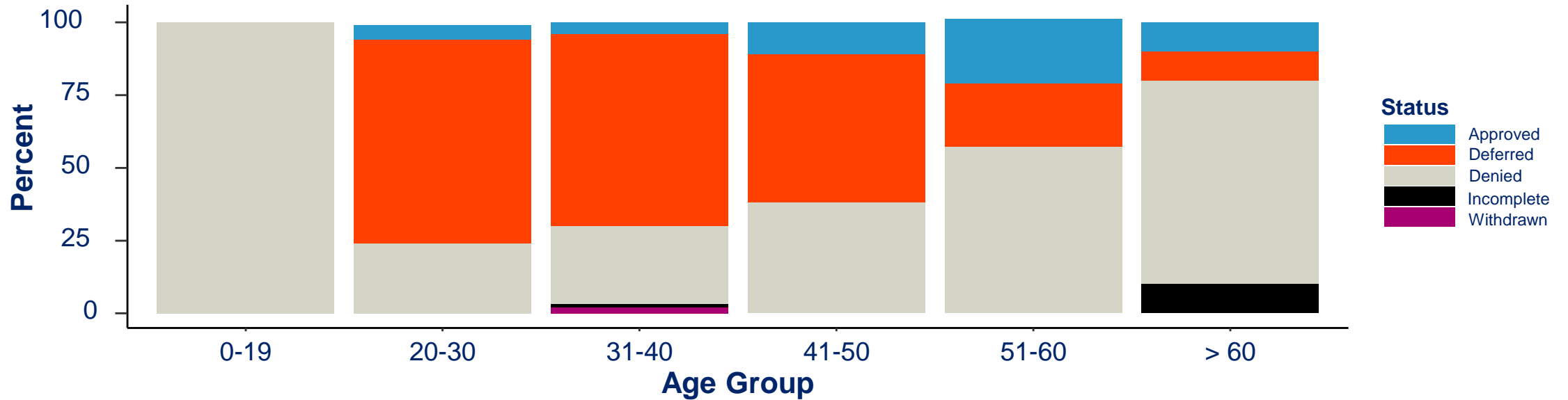
- **Approved**—exemption has a start date but no end date*
- **Deferred**—exemption has a start and an end date*
- **Exemption status is as of 12/19/2022 and may have changed since then**

*See appendix for complete definitions

Source: Cority
Date data was pulled: 12/19/2022

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Medical Exemption Status by Age Group for Initial Vaccine Series



*This figure illustrates the proportion of exemption of each age group

Source: Cority
Date data was pulled: 12/19/2022

Reason for Request for Medical Exemption from Initial Vaccine Series

Exemption Reason	Female	Male	Total
Other	82	20	102
Pregnancy	53	0	53
Active COVID-19 Infection	10	5	15
Active Fertility Treatment	13	0	13
Vaccine Allergy (mRNA, J&J)	10	2	12
Monoclonal Antibody or Convalescent Plasma	7	2	9
Active Quarantine	4	1	5
Unknown	4	1	5
Total	183	31	214

*Exemption reasons for female and male have similar proportions except for active COVID-19 Infection

Approved Medical Exemptions for Initial Vaccine Series

Exemption Reason	Count
Cardiac	4
Vaccine Allergy (mRNA, J&J)	9
Other	5
Total	18

Approved Allergy Documentation for Medical Exemptions

Select notes from the interactive process:

- PEG/Polysorbate 80 allergy – skin testing performed, confirmed
- Observed or objective evidence of allergic reaction to available COVID-19 vaccines
- Emergency Department treatment of anaphylaxis, hospitalization

Approved “Cardiac Related” Exemptions

Select notes from interactive process:

- High risk pericarditis, congenital heart disease, chest pain
- Chest pain and SOB with hospitalization following vaccine
- Life threatening arrhythmia after 1st vaccine, if re-vaccinate cardiologist recommends monitoring for 24-48 hours
- Malignant HTN requiring hospitalization after first dose

Approved “Other” Reasons for Medical Exemption

Select notes from interactive process:

- Major flareup of multifocal choroiditis/posterior uveitis worsening vision
- Negative allergy testing, vaccine reaction likely due to chronic idiopathic urticaria persistent severe flare
- Radiation therapy damage with bi-lateral upper extremity chronic neuropathy that may worsen with vaccine, as well as the concern of the radiation oncologist that vaccination may worsen the condition
- Autoimmune encephalitis requiring hospitalization after vaccine
- Persistent painful hematoma following first dose in patient with hemophilia A
- Worsening GVHD induced by first dose of vaccine, h/o bone marrow transplant at MSK

Approved Medical Exemptions for Booster

Exemption Reason	Count
Cardiac	3
Vaccine Allergy (mRNA, J&J)	4
Other	8
Total	15

Notes:

- Requirements for booster changed state to state and over time

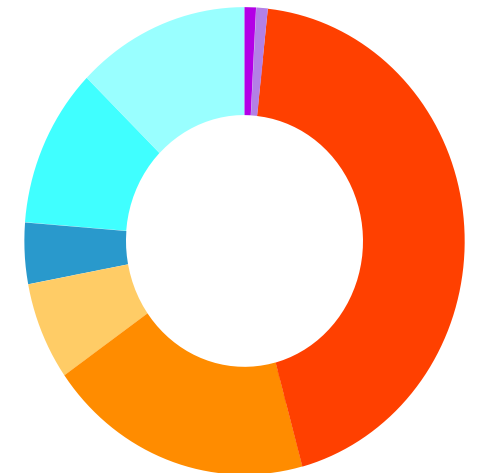
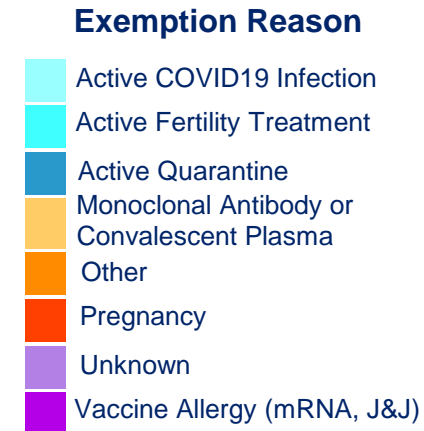
COVID-19 Initial Vaccine Series Deferred Exemptions

What was the outcome for employees whose COVID-19 vaccination was deferred?

Work Status	Deferred	Vaccinated	Total
Active Duty	19	89	108
On Leave	9	1	10
Total	28	90	118

Notes:

- Majority of deferred exemptions: Pregnancy, active COVID-19 infection, and other
- Most workers with deferred exemptions are active duty



Questions/Comments?



Thank you!

Acknowledgments

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Manager, Workers' Compensation and Workplace Accommodations

Katie Todd, MPH

Director, Employee Health

Stephanie DeFrank, MS

Business Intelligence Analyst I

Medical Exemption Review Committee, Specialists the following departments

- Employee Health / Occupational Medicine
- HR Legal and Regulatory Affairs
- Medicine
- Infection Control
- Infectious Disease
- OB Gyn
- Cardiology
- Ethics
- Allergy & Immunology
- Critical Care

Appendices:

- Terminology
- COVID-19 Select Events Timeline
- COVID-19 Vaccination Policy
- State mandates and Booster Shot Requirement
- Eligibility and Medical Exemption to COVID-19 Vaccine

Terminology

- **Approved**—exemption status has a start date but no assigned end date. EE receives a notification that request is approved and should a new vaccine be developed; EE may be required to receive it unless they have a new approved exemption.
- **Deferred**—the condition for which the medical exemption was approved is of limited duration or condition may change and requires review, the exemption has a start and an end date.
- **Denied**—the reason for the requested medical exemption did not meet eligibility criteria
- **Incomplete**—a portion of the medical exemption request forms was submitted but all of the required fields or documentation was not complete
- **Withdrawn**—employee indicated they no longer would like to apply for exemption after having submitted a medical exemption request

[COVID-19 Vaccination Policy](#)

Covid-19 Select Events Timeline

- **March 15, 2020:** States begin to implement shutdowns in order to prevent the spread of COVID-19. The **New York City public school system**— the largest school system in the U.S., with 1.1 million students— **shuts down**
- **April 20, 2020:** **Shortages** of personal protective equipment (**PPE**) like gowns, eye shields, masks, and even body bags, become dire— particularly in New York
- **April 30, 2020:** The Trump Administration launches **Operation Warp Speed**, an initiative to produce a **vaccine** against the SARS-CoV-2 virus as quickly as possible.
- **December 11, 2020:** FDA issues an **EUA for the Pfizer-BioNTech COVID-19 vaccine**.
- **December 18, 2020:** FDA issues an **EUA for the Moderna COVID-19 vaccine**.
- **December 22, 2020:** CDC releases a report in *MMWR* outlining the ACIP’s recommendations for the “**phases**” of **COVID-19 vaccination allocation while supply is still limited** in the U.S. The suggested model for efficient and equitable vaccination distribution: **phase 1a – healthcare personnel...**
- **December 29, 2020:** The first case of the COVID-19 B.1.1.7 / “**Alpha**” **variant** is detected in the U.S. by the Colorado Department of Health.
- **January 25, 2021:** The first case of the COVID-19 P.1 / “**Gamma**” **variant**, first identified by scientists in Brazil, is detected in Minnesota.
- **January 28, 2021:** The first case of the COVID-19 B.1.351 / “**Beta**” **variant**, first identified by scientists in South Africa, is detected in South Carolina.
- **February 21, 2021:** The recorded COVID-19 **death toll in the U.S. surpasses 500,000**.
- **February 27, 2021:** FDA approves an emergency use authorization (**EUA**) for **Johnson & Johnson’s** one-shot COVID-19 vaccine for all people ages 18 years and older.
- **March 13, 2021:** More than 100 million COVID-19 vaccine doses have been administered in the U.S.
- **March 25, 2021:** CDC announces **\$300 million** in funding for states, localities, territories, tribes, and tribal organizations for community health worker (CHW) services to address: 1) **disparities in access to COVID-19 related services**, such as testing, contact tracing, and immunization; 2) factors that increase risk of severe COVID-19 illness, such as chronic diseases, smoking, and pregnancy; and 3) community public health needs that have been exacerbated by COVID-19, such as **health and mental health care access and food insecurity**.

<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6912a1.htm>
<https://www.fda.gov/emergency-preparedness-response-recovery/medical-products/updates/2021/03/2021-03-25-cdc-announces-300-million-in-funding-for-states-localities-territories-tribes-and-tribal-organizations-for-community-health-worker-chw-services-to-address-1-disparities-in-access-to-covid-19-related-services-such-as-testing-contact-tracing-and-immunization-2-factors-that-increase-risk-of-severe-covid-19-illness-such-as-chronic-diseases-smoking-and-pregnancy-and-3-community-public-health-needs-that-have-been-exacerbated-by-covid-19-such-as-health-and-mental-health-care-access-and-food-insecurity>

Covid-19 Select Events Timeline (continued)

- **March 29, 2021:** A CDC study finds that mRNA COVID-19 vaccines, Pfizer-BioNTech and Moderna, are **highly effective at preventing infection with the SARS-CoV-2 virus in real-world conditions among healthcare personnel**, first responders, and other essential workers (groups that are more likely than the general population to be exposed to the virus because of their occupations), reducing their risk of infection by 90%.
- **April 3, 2021:** CDC announces **\$3 billion** in additional funding for expanded COVID-19 **vaccination programs**.
- **April 8, 2021:** CDC Director Dr. Rochelle Walensky releases a statement on racism and health amid the COVID-19 pandemic, writing: “Yet, the disparities seen over the past year were not a result of COVID-19. Instead, the **pandemic illuminated inequities that have existed for generations and revealed for all of America a known, but often unaddressed, epidemic impacting public health: racism.**”
- **April 21, 2021:** More than 200 million COVID-19 vaccine doses have been administered in the U.S.
- **April 23, 2021:** ACIP and FDA recommend the continued use of Johnson & Johnson’s COVID-19 vaccine for all people ages 18 years and older in the U.S., following a thorough safety review after the use of the vaccine was paused when 6 cases of rare and severe type of blood clots were reported.
- **April 28, 2021:** CDC finds that the Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines reduce the risk of hospitalization with SARS-CoV-2 in people ages 65 years and older by 94%.
- **May 12, 2021:** ACIP recommends the Pfizer-BioNTech COVID-19 vaccine for all adolescents ages 12–15 years.
- **June 1, 2021:** The COVID-19 B.1.617.2 / “**Delta**” variant, first identified in India, becomes the **dominant variant in the U.S.** The variant begins a **third wave** of infections during the summer of 2021.
- **June 7, 2021:** CDC finds that the Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines reduce the risk of infection with the SARS-CoV-2 virus by 91% and protect against severe illness and hospitalization if a breakthrough infection does occur.
- **July 27, 2021:** Amid a Delta variant surge, CDC releases updated masking guidance recommending that everyone in areas with substantial or high transmission wear a mask indoors.
- **July 30, 2021:** CDC releases data in *MMWR* showing an **increase in breakthrough infections** of COVID-19 in Barnstable County, Massachusetts in July of 2021. The early data showing high viral loads in people infected with the Delta variant of COVID-19 suggest a concern that, **unlike with other variants, vaccinated people infected with Delta can transmit the virus to others.** This *MMWR* becomes the most widely circulated report in the agency’s history.
- **August 6, 2021:** CDC releases data in *MMWR* showing that **unvaccinated individuals are more than twice as likely to be reinfected with COVID-19 than those who were fully vaccinated** after initially contracting the virus – in other words, COVID-19 vaccines offer stronger protection than natural immunity alone
- **August 11, 2021:** CDC releases a statement assuring the public that COVID-19 vaccination is **safe for pregnant and breastfeeding people.** CDC studies have found that an infection with COVID-19 during pregnancy increases the risk of developing severe illness from COVID-19 and that there is **no evidence that any vaccines, including the COVID-19 vaccines, cause fertility problems in women or men.**

Source:

[https://urldefense.com/v3/https://www.cdc.gov/museum/timeline/covid19.html_!!KVVWo1iE!W5NIGI9IUqes_HERRBwBJO7i5s8wRu0IPhtsfUmBT0nhfZMeUn2mR41ddVhmr0kJcncd8qOxUY7R8nw\\$](https://urldefense.com/v3/https://www.cdc.gov/museum/timeline/covid19.html_!!KVVWo1iE!W5NIGI9IUqes_HERRBwBJO7i5s8wRu0IPhtsfUmBT0nhfZMeUn2mR41ddVhmr0kJcncd8qOxUY7R8nw$)

Covid-19 Select Events Timeline (continued)

- **August 18, 2021:** HHS, CDC, and FDA release a statement concluding that **booster shots** of the Pfizer-BioNTech, Moderna, and Johnson & Johnson COVID-19 vaccines will be **needed** to protect against severe disease, hospitalization, and death in the coming months.
- **September 29, 2021:** CDC issues an **urgent health advisory to increase COVID-19 vaccination rates among people who are pregnant, breastfeeding, or who are trying to become pregnant**. More than 22,000 pregnant people have been hospitalized with COVID-19 and 161 have died. COVID-19 in pregnant people carries a two-fold risk of admission to intensive care, a 70% increased risk of death, and adverse pregnancy outcomes that can include preterm birth, stillbirth, and the admission of a newborn into the ICU with COVID-19
- **October 6, 2021:** WHO publishes a clinical case definition of “post COVID-19 condition” or **long COVID**. The symptoms of long COVID include, but are not limited to, fatigue, shortness of breath, and / or cognitive dysfunction that persists for at least two months and impacts everyday life, three months from the onset of an initial COVID-19 infection.
- **November 19, 2021:** Amid **worries of an upcoming Omicron** surge, CDC strengthens its recommendation urging that everyone ages 18 years and older who received a Johnson & Johnson, Pfizer-BioNTech, or Moderna COVID-19 vaccine should receive a booster after they are fully vaccinated.
- **December 1, 2021:** The first case of the **Omicron** variant in the U.S. is detected by the California and San Francisco Departments of Public Health.
- **December 9, 2021:** CDC and FDA expand COVID-19 **booster recommendations** to include everyone ages 16 years and older.
- **January 1, 2022:** As Delta and Omicron spread, **New York state records its highest number of new COVID-19 cases in a single day** since the pandemic began – with 114,082 new confirmed cases.
- **January 14, 2022:** CDC updates guidelines on masks to emphasize fit, comfort, and consistent wear.
- In one month, the daily average of **new COVID-19 infections** reported in the U.S. **spikes from 119,215 to 805,062**.
- **February 11, 2022:** CDC releases **data** showing that COVID-19 vaccine **boosters** remain **safe** and were **highly effective against severe disease during the Omicron and Delta variant surges** for everyone ages 5 years and older. CDC releases data in *MMWR* showing that the Omicron variant rose from 1% of all infections in the U.S. to 99% of all infections in just 6 weeks (compared to 18 weeks for Delta).

Source:

[https://urldefense.com/v3/https://www.cdc.gov/museum/timeline/covid19.html#!KVVW01iE!W5NIGI9IUqes_HErRBwBJO7i5s8wRu0IPhtsfUmBT0nhfZMeUn2mR41ddVhmr0kJcncd8qOxUY7R8nw\\$](https://urldefense.com/v3/https://www.cdc.gov/museum/timeline/covid19.html#!KVVW01iE!W5NIGI9IUqes_HErRBwBJO7i5s8wRu0IPhtsfUmBT0nhfZMeUn2mR41ddVhmr0kJcncd8qOxUY7R8nw$)

State Mandates and Booster Shot Requirements

- New Jersey's COVID-19 booster requirement took effect on **April 11, 2022**. All New Jersey-based staff (as coded in Workday) who were eligible to receive a COVID-19 booster must have received a booster or have an approved exemption (medical or fully remote) by Monday, April 11 to continue working at MSK, as mandated by New Jersey. The application process for COVID-19 vaccination booster medical exemptions is the same as outlined above for COVID-19 vaccination medical exemptions.
- New Jersey-based staff (as coded in Workday) not yet eligible for a booster must meet these criteria within three weeks of becoming eligible, as mandated by New Jersey.
- On **February 18, 2022**, **New York State** announced it **will not require** health care workers to get their COVID-19 Vaccination Booster by February 21, 2022, as previously mandated. MSK's medical **exemption** from the COVID-19 vaccination **booster** for New York State employees has been put **on hold** accordingly. New York's COVID-19 vaccine mandate remains in effect.

COVID-19 vaccine medical exemption eligibility

- **Conditions currently eligible for medical exemptions**, include, but are not limited to*:
 - ✓ Documented history of severe allergic reaction to a component of each currently available COVID-19 vaccine
 - ✓ Documented history of severe or immediate-type hypersensitivity allergic reaction to a COVID-19 vaccine, and separate contraindication to other available formulations

*Reasons for medical exemptions may be updated as new information is obtained.



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