




COVID-19

UPDATE:
December 4, 2020

**Coronavirus / COVID-19
Response Team**


MILLER 
JOHNSON
Attorneys

1

MILLER 
JOHNSON
Attorneys

**COVID-19 Vaccine Part 2:
Vaccine Considerations for
Employers**

» Sarah Willey
Tripp VanderWal

MILLER 
JOHNSON
Attorneys

The materials and information have been prepared for informational purposes only. This is not legal advice, nor intended to create or constitute a lawyer–client relationship. Before acting on the basis of any information or material, readers who have specific questions or problems should consult their lawyer.

Today's Topics

- Overview of timing and availability of vaccine
- Emergency Use Authorization/safety
- Considerations for mandating vaccine
- Potential side effects
- Coverage of the COVID-19 vaccine by group health plans

Comparison of current COVID-19

Manufacturer	Vaccine Type	EUA Timeline	Availability	Cost
Pfizer-BioNTech	mRNA	Likely EUA date: December 10, 2020	~50 million doses by year end	\$19.50 for the first 100 million doses
Moderna				\$25-37 per dose
AstraZeneca-Oxford	Adenovirus-based	Possibly January 2021	Potentially 30 million by year end	\$3 per dose (but variable by market)
Johnson & Johnson	Adenovirus-based	Possibly March or April 2021	Projected 1 billion by end of 2021	\$10 per dose

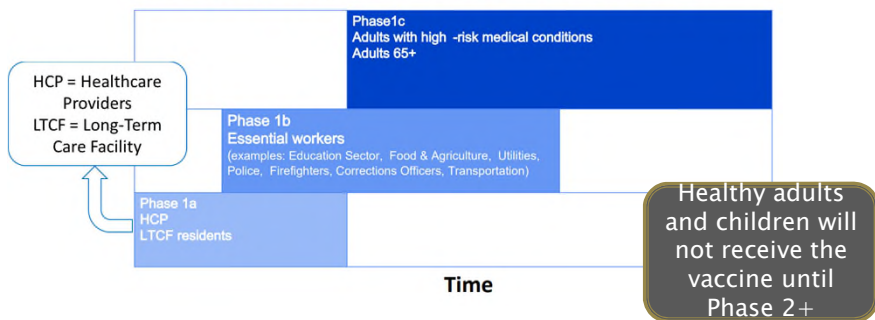
<https://www.biospace.com/article/comparing-covid-19-vaccines-pfizer-biontech-moderna-astrazeneca-oxford-j-and-j-russia-s-sputnik-v/>

Timing and Availability

- Vaccine is government allocated
 - Employers have limited access
 - Employers have no control over who gets it when
- CDC is working with various jurisdictions – including all 50 states – to allocate what is currently available
- Michigan (DHHS) has its own COVID-19 Vaccination Plan

Phased Allocation of COVID-19 Vaccine (CDC)

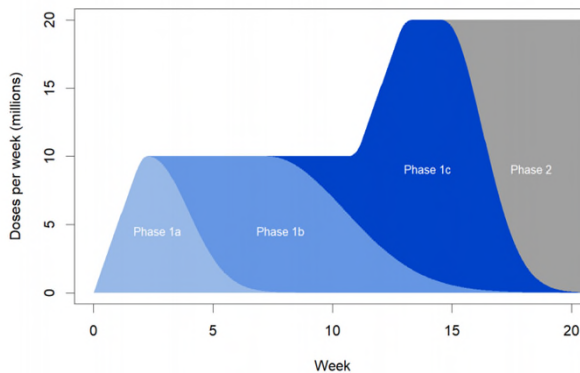
Work Group Proposed Interim Phase 1 Sequence



<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-11/COVID-04-Dooling.pdf>

Example of a Possible Phase 1 Sequence

Access to both doses (where applicable) will be ensured for those qualifying before access is granted to subsequent phases



<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-11/COVID-04-Dooling.pdf>

Michigan's Vaccine Plan

- Initial allocations will be sent directly to hospitals and hospital systems for health care workers
 - Later allocations will be managed by local health departments, which will establish distribution sites, likely health providers, off-site clinics and pharmacies

Michigan's Vaccine Plan

- **Phase 1:** Healthcare workers who have the potential for direct or indirect exposure; long-term care staff and residents; first responders; those over 65 who may be at high risk for severe complications; water, light, power and EMS
- **Phase 2:** Essential grocery and food distribution workers; healthcare not in Phase 1; high risk populations; potentially other critical infrastructure employees
- **Phase 3:** General population

Michigan's Vaccine Plan

- Local health departments will work with employer groups to form partnerships to assure that employers have a mechanism to obtain vaccinations
- Local health departments will be encouraged to have clinics for employers that do not have a mechanism to vaccinate employees
 - Likely same as current COVID testing sites

Vaccine Mandation

- This situation is unprecedented
 - Global pandemic
 - Effort to give vaccine under Emergency Use Authorization to millions (billions) of people
 - Federal conditions for EUA include that recipients are informed of the option to accept or refuse administration of the product
 - Limited availability
 - Employers do not control who gets it when
- For many employers, we will have more information and answers before making this decision

Vaccine Mandation

- What we know now
 - ADA/Title VII analysis based on flu vaccine
 - Largest consideration; required process
 - EEOC has not yet spoken regarding COVID vaccine
 - OSHA guidance based on flu vaccine
 - 2009 letter: can mandate but are not required to do so
 - Collective bargaining agreements
 - NLRA/anti-vax movement in the workplace
 - Beware of protected and concerted activity
 - State privacy laws

ADA Medical Examinations

- Courts have treated vaccinations as “medical exams” under the ADA
 - Must be job related and consistent with medical necessity
- Could be an issue if vaccine not safe and effective
- Based on EEOC’s current guidance regarding COVID testing, health assessments, etc., they likely would defer to the CDC and FDA.

ADA Reasonable Accommodation

- Employees with ADA-covered disability may be entitled to exemption if disability prevents them from safely taking the vaccine
- Establish interactive reasonable accommodation process
 - Can require medical documentation
- Employers can select alternative accommodations (e.g., masks, barriers, protective gear, etc.)
 - Exclusion from workplace a last resort

ADA Reasonable Accommodation

- Not required to accommodate if undue hardship
 - Current public health and economic circumstances relevant to this analysis

Title VII Religious Accommodation

- Title VII requires employers to reasonably accommodate an employee's sincerely held religious beliefs
 - Unless it would be an undue hardship on business operations
 - Undue hardship is "more than *de minimis* cost," which is much lower standard than under the ADA

Title VII Religious Accommodation

- Focus is usually on undue hardship
- Religion = moral or ethical beliefs as to right or wrong that are sincerely held with the strength of traditional religious views.
 - Religious beliefs generally concern "ultimate ideas" about "life, purpose and death."
 - More than personal preferences, medical beliefs and political philosophies
 - Does not have to be widely practiced

Title VII Religious Accommodation

- Examples
 - “Our bodies are a temple and God gave us dominion over our bodies”
 - “Injecting the flu vaccine into my body is morally wrong”
 - “Followers of my religion are healed by plants, fruits and grains”
- Can require additional supporting documentation if there is objective basis for questioning the religious nature or the sincerity of a belief.

Other Potential Concerns

- Side effects – even if minor, might trigger isolation requirements (e.g., fever)
 - Allow exception to PA 238/MIOSHA Rules with medical clearance?
- Schools/students
 - Current School Code
 - MDHHS issues rules on which diseases are subject to an immunization requirement
 - Usually prior to first enrollment and before entering 7th grade
 - Likely will not be decided until Spring

Coverage of the COVID-19 Vaccine By Group Health Plans

ACA Preventive Care Mandate - Background

- Non-grandfathered group health plans are required to provide certain preventive care items and services on a “first-dollar” basis (i.e., without participant cost-sharing)
- For plans that utilize a network, the mandate only applies to in-network providers (assuming participants can obtain the required preventive care items and services from in-network providers)

ACA Preventive Care Mandate - Background

- The required preventive care items and services include:
 - Evidence-based items or services with an “A” or “B” rating by the USPSTF
 - Immunizations for **routine use** for children, adolescents, or adults recommended by the CDC’s ACIP
 - Evidence-based preventive care and screenings supported by the HRSA for infants, children, adolescents and women

ACA Preventive Care Mandate - Background

- Coverage based on new ratings or recommendations:
 - These preventive care items and services must be covered on a first-dollar basis beginning the first plan year that begins on or after the date that is one year after the new rating or recommendation is issued
 - For example, a calendar year plan must cover preventive care during the plan year beginning January 1, 2021 if the rating/recommendation was issued on or before January 1, 2020

ACA Preventive Care Mandate - Background

- Preventive care provided during office visits:
 - Cost-sharing for office visits is permitted when preventive care services are billed separately or are not the primary purpose of the office visit
 - Ex. Office visit to discuss abdominal pain and a BP screening is administered; PCP bills the BP screening separately from the office visit – Cost-sharing permitted for office visit but not BP screening
 - Ex. Same facts except PCP does not bill BP screening separately from office visit – Cost-sharing permitted
 - Ex. Office visit for BP screening but discusses abdominal pain during visit; PCP does not bill separately – No cost-sharing permitted

ACA Preventive Care Mandate – COVID-19 Vaccine

- CARES Act
 - Requires non-grandfathered group health plans to cover on a first-dollar basis a “qualifying coronavirus preventive service” (QCPS), which is an item, service or immunization (including the **administration** of the immunization) that is intended to prevent or mitigate COVID-19 and has:
 - A rating of “A” or “B” by the USPSTF
 - A recommendation by the CDC’s ACIP (even if not for “routine use”)

ACA Preventive Care Mandate – COVID-19 Vaccine

- Coverage must begin within 15 business days of the QCPS receiving the “A” or “B” rating, or recommendation
- During the public health emergency (PHE) declared by HHS, QCPS must be also be covered when provided by out-of-network providers:
 - For out-of-network providers, the reimbursement to the provider must be reasonable (e.g., the Medicare reimbursement rate)
 - Providers who receive the vaccine for free from the federal government are prohibited from balance billing patients

ACA Preventive Care Mandate – COVID-19 Vaccine

- Other comments:
 - Grandfathered health plans are not required to cover the COVID-19 vaccine at all or on a first-dollar basis, but are encouraged to do so. (Note: grandfathered health plans are still required to cover COVID-19 diagnostic testing with no cost-sharing during the PHE declared by HHS)
 - QCPS can be provided by HDHPs before the minimum deductible is satisfied without jeopardizing participants’ HSA eligibility

ACA Preventive Care Mandate – COVID-19 Vaccine

- The vaccine will generally be paid by the federal government under the CARES Act. In most cases, a plan will only be required to pay for the administration of the vaccine (this is not true for non-vaccine QCPS)
- For all preventive care services, the preamble clarifies that cost-sharing is not permissible for items or services that are **integral** to the provision of the preventive care (including office visits that are billed separately). For example, a diabetes screening is generally performed by a lab, but an office visit is usually required for specimen collection

ACA Preventive Care Mandate – COVID-19 Vaccine

- Most of the requirements for covering QCPS as a preventive care service will “sunset” upon the expiration of the PHE
 - If a QCPS satisfies the definition of preventive care after the PHE, coverage may need to continue
- Employer payments for vaccine outside of a group health plan:
 - Employee incentives (which may be taxable) to receive the vaccine may be permissible
 - Reimbursement for the cost and administration of the vaccine **may** create an employee welfare benefit plan subject to ERISA and the Internal Revenue Code

MILLER JOHNSON
Attorneys



Sarah Willey
269.226.2957
willey@millerjohnson.com



Tripp VanderWal
616.831.1796
vanderwalt@millerjohnson.com

millerjohnson.com

45 Ottawa Ave SW
Suite 1100
Grand Rapids, MI 49503

100 W Michigan Ave
Suite 200
Kalamazoo, MI 49007

409 E. Jefferson Ave
Fifth Floor
Detroit, MI 48226

31

Resource Center

<https://resources.millerjohnson.com/>

MILLER JOHNSON
Resource Center

Our redesigned, online **Resource Center** is one of the highest value propositions we've ever offered to clients and members of the business community. You get 6 months of unlimited access, for the cost of a few hours of legal counsel, to an extensive collection of material across our employment and labor, business and corporate, and litigation practices.

Now featuring 18 sections with content organized by subject for easy reference including topics like FFCRA, Preparedness Plans, Reductions in Force, Safety, and Telecommuting as well as industry specific guidance, the **Resource Center** serves as a blueprint for businesses.

Whether you are returning your workforce after disruption, establishing new protocols, or continuing operations and looking for a one-stop shop for decision-making tools, the Resource Center serves as an on-demand, self-serve library of legal solutions without incurring hourly fees.

Subscribe
Log In

Here is a sampling of what is covered by your organization's subscription:

Guidance Contact Account Log in

