OMIC
OPHTHALMIC MUTUAL INSURANCE COMPANY
A Risk Retention Group

Risk Management Recommendations

Sponsored by the American Academy of Ophthalmology

COVID-19 Vaccine

Purpose of risk management recommendations

OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology's *Preferred Practice Patterns*, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they provide legal advice. Consult an attorney if legal advice is desired or needed. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

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Introduction

OMIC insureds have expressed interest in contributing to the nationwide COVID-19 vaccination effort, either by volunteering to administer the vaccine in their communities or by making the vaccine available to their patients and staff. Vaccination services are complex, and can be additionally challenging for physicians who do not customarily vaccinate patients. Some challenges are logistical, and others can impact patient safety and increase physician liability exposure. OMIC has been carefully monitoring this situation since the first COVID-19 vaccine was approved. Although the Public Readiness and Emergency Preparedness (PREP) Act provides liability immunity, it is not unlimited. Vaccination services may still result in lawsuits or claims. OMIC is extending coverage to its insureds for the administration of COVID-19 vaccinations. Questions about coverage should be directed to OMIC's Underwriting Department at (800) 562-6642, ext. 1, or omic@omic.com.

This document outlines some initial, logistical considerations, but focuses on medical professional liability risks associated with offering the COVID-19 vaccine and recommendations to mitigate those risks. The goal is to support safe patient care and reduce liability exposure. We strongly recommend that our insureds implement these recommendations. In addition to protecting patients, these recommendations, combined with the protections afforded under the PREP Act, will allow OMIC to limit exposure to our company and better defend claims should they arise.

Initial Considerations

Administering and monitoring vaccines carry significant responsibility. The COVID-19 vaccine adds additional layers of complexity to the process. The areas listed below represent some of those responsibilities. (Source: COVID Collaborative and the Ad Council. Health care leaders share COVID-19

vaccination logistics. January 10, 2021. [Video]. Available at: https://www.healio.com/news/primary-care/20210113/video-health-care-leaders-share-covid19-vaccination-logistics (Accessed: 1/19/21))

Be aware that some state medical boards are prioritizing the discipline of doctors who engage in the diversion of COVID-19 vaccine or vaccine-administration supplies provided by the federal government, in violation of applicable federal and state guidance, for financial gain. You can access your state medical board here: https://www.fsmb.org/contact-a-state-medical-board/.

Eligibility

Local jurisdictions coordinate the federal COVID-19 vaccination program. Ophthalmology practices interested in administering the COVID-19 vaccine at their sites will need to register with their state or local health departments to implement the program.

The Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Operational Guidance includes links to each state's vaccination program executive summary. Healthcare providers can find guidance for different aspects of their state's vaccination program within those summaries. (See: COVID-19 Vaccination Program Interim Operational Guidance for Jurisdictions Playbook. Available at: https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html (Accessed: 1/20/21))

Availability

The federal government distributes vaccines to the states; your ability to participate as a vaccine provider may depend on the availability and distribution in your area.

Storage and Handling

The program with which you register will likely provide guidance on vaccine storage. In some jurisdictions, health departments might coordinate storage, while in others, you may be responsible for storing the vaccine at the appropriate temperature. Different vaccines will have different temperature requirements, so it is imperative to follow the manufacturer's guidance. The CDC provides advice on vaccine storage and handling best practices, a training module for healthcare professionals, and reference material in the COVID-19 Vaccine Training Module for Healthcare Professionals. (Accessed: 1/15/21)

Staff Training

The CDC recommends that "all health care personnel who administer vaccines receive comprehensive, competency-based training on vaccine administration policies and procedures **before** administering vaccines. Comprehensive, skills-based training should be integrated into existing staff education programs, such as new staff orientation and annual education requirements." (Source: CDC. Vaccine Administration. Available at: https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html (Accessed: 2/2/21))

Reporting Requirements

Vaccination providers must report their inventory daily to VaccineFinder. For more information, see the CDC's "COVID-19 Vaccination Reporting Systems":

- VaccineFinder. Available at: https://www.cdc.gov/vaccines/covid-19/reporting/vaccinefinder.html (Accessed: 2/2/21)

- Provider Enrollment Guidance. Available at: https://www.cdc.gov/vaccines/covid-19/reporting/requirements/support-for-providers.html (Accessed: 2/2/21)

Key Takeaways

- Understand the requirements of the federal government's COVID-19 vaccination program, and what your local jurisdiction requires for you to be compliant.
- Assess whether you have the resources and capability to comply fully with requirements. If you determine you are not able to meet requirements, investigate other ways to contribute (e.g., volunteering at other health systems or registered sites).
- If you proceed with becoming a vaccine provider, have one of your staff members act as a vaccine coordinator. This person should monitor guidance and resources from agencies such as state and local health departments, the CDC, and the FDA.

Managing Professional Liability Risks

Managing COVID-19 vaccination is complex: there is more than one manufacturer of the vaccine, and each will have specific instructions; the vaccination rollout is done in phases and tiers, which can change, depending on jurisdictions; some vaccines may be available as a single dose, while others require two doses, and the interval between doses may differ among manufacturers, which requires vaccinators to be especially vigilant in their patient education and follow-up. And, because the vaccine is new, information about reactions is continually changing, which can affect the distribution and availability of vaccines, the interval between the first and second doses, and the possibility that the second dose could be from a different manufacturer. These factors call for providers to have an overall plan in place, and also pay attention to detail.

Key risk management concerns associated with offering COVID-19 vaccines include informed consent; post-vaccination monitoring; responding to adverse reactions; tracking and follow-up; medical record documentation; physician supervision of staff administering injections; and the nature of the physician-patient relationship. Review the following information and, as with the logistical aspects discussed above, evaluate whether offering these vaccinations is within your capabilities. If you determine that it is, adherence to risk management principles should help to keep patients safe and reduce your liability exposure.

Informed Consent and Refusal

If the ophthalmologist does not have an adequate consent discussion with the patient and document it, and the patient suffers a complication or reaction, that patient could initiate a claim against the physician, alleging that they never would have accepted the vaccination had they known about potential complications.

Risk Management Recommendations

- Provide the patient with the COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers, and document that you did so.
    - Use the EUA Fact Sheet that applies to the vaccine being administered (e.g., Pfizer BioNTech or Moderna). Available at: https://www.cdc.gov/vaccines/covid-19/eua/index.html (Accessed: 1/20/21). These Fact Sheets are similar to Vaccine Information Sheets (VIS); however, they are vaccine-specific, developed by the vaccine manufacturer, and authorized by the FDA. Vaccine Information Sheets will be available

when licensed vaccines (i.e., not EUA vaccines) become available.

- Clearly communicate risks associated with the vaccine, taking into consideration patient-specific risks (e.g., contraindications related to patient comorbidities or prior reactions to vaccines).
- Talk with patients about common side effects (e.g., fever, pain, headache, fatigue, aching at the injection site).
- Communicate the schedule for the COVID-19 vaccination (i.e., need for a second dose). Refer to the CDC for information, as the different manufacturers have different schedules.
- Document in the medical record your discussion with the patient, and the patient's understanding of risks and benefits, the need for a second dose, and the limited efficacy of a single dose in the event the patient fails to return for a second dose.
- In addition to documenting in the medical record, use a consent form: https://www.omic.com/wp-content/uploads/2021/02/COVID-Vaccine-Sample-Consent.docx
- Prior to administering the vaccine, provide the patient with information about reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS): https://vaers.hhs.gov/faq.html

Monitoring for Allergic or Adverse Reactions

Ophthalmologists who decide to provide vaccines will also be taking on the risk of handling emergencies that they rarely, if ever, need to manage in their routine clinical practices. Inadequate preparation to manage a life-threatening reaction to the vaccine could result in patient harm and liability exposure for the physician. The ophthalmologist or other personnel on site must have advanced training in the management of medical emergencies and the ability to respond to such emergencies.

Risk Management Recommendations

- Ensure that your office has a plan for responding to medical emergencies, including having emergency equipment and personnel with advanced training in the management of such emergencies.
- The CDC provides a list of equipment and medication that should be available at all sites: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fanaphylaxis-management.html (Accessed: 1/26/21)
- Adhere to the vaccine manufacturer's guidance regarding time to monitor the patient post-injection.
- When you are ready to release the patient, provide them with information about symptoms of concern and adverse reactions associated with the particular vaccine.
- Instruct patients to call 911 or go to the emergency room immediately if they are experiencing life-threatening symptoms.
- If a patient should call your office, document the symptoms reported, the vaccine the patient received and the date received, and your instructions to the patient (e.g., call 911, go to the emergency room).

The CDC provides guidance for handling adverse reactions at: Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites. (Accessed: 1/15/21)

Reporting Adverse Reactions

OMIC Reporting

- Report severe side effects or complications to OMIC. Direct your report to: Ryan Bucsi, Vice President, Claims at (415) 202-4620, or rbucsi@omic.com.
- For assistance communicating with the patient about an adverse reaction, contact OMIC's Risk Management Hotline at (800) 562-6642 (Press 4), or riskmanagement@omic.com.

Vaccine Adverse Event Reporting System (VAERS)

- **Healthcare providers must report the following adverse events (AEs) after COVID-19 vaccination to the VAERS:**
    - Vaccine administration errors, whether or not associated with an adverse event (AE)
    - Serious AEs regardless of causality. Serious AEs per the FDA are defined as:
        - Death
        - A life-threatening AE
        - Inpatient hospitalization or prolongation of existing hospitalization
        - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
        - A congenital anomaly/birth defect
        - An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
    - Cases of Multisystem Inflammatory Syndrome
    - Cases of COVID-19 that result in hospitalization or death
    - Any additional select AEs and/or revised safety reporting requirements per the FDA's conditions of authorized use of COVID-19 vaccines under an Emergency Use Authorization
- Healthcare providers are strongly encouraged to report:
    - Any additional clinically significant AEs following vaccination, whether or not it is clear that the vaccination caused the event

(Source: https://vaers.hhs.gov/faq.html (Accessed: 1/19/21)

Patient Follow-Up for Vaccines Requiring a Second Dose

If the practice does not have a follow-up system in place to ensure that patients receive their second dose of the vaccine and a patient develops COVID-19, he or she could initiate a claim against the ophthalmologist alleging that the ophthalmologist either did not inform them of the need for a second dose or did not contact them to get it. Patients cannot be forced to return for a second dose; however, the practice's use of a follow-up tracking mechanism – ***and its documented attempts to contact patients*** – demonstrate that the physician made reasonable efforts to ensure continuity of care.

Risk Management Recommendations

- Implement a follow-up system. Appointment tracking and patient recall capabilities may be built into your EHR, but remember that the system requires monitoring, action, and accountability (i.e., it is not enough to assume that the EHR will do the work for you).
- Have a system in place to follow up with patients who cancel appointments without rescheduling. If the appointment is for the second dose, inform the patient of the limited

efficacy of a single dose. Similarly, if a patient refuses a second dose, discuss the potential limited effect of one dose. If the patient still refuses, document the refusal and the patient's understanding of what you discussed.

- Your follow-up system can involve calling the patient and documenting the results of the attempt. You may elect to follow the call with a letter stating your attempts to recall the patient and emphasizing the benefits of the second dose. Keep a copy of the letter in the patient's chart.
- Document if a patient chooses to receive the second dose elsewhere.

Documentation

Documentation is the record of the care you provided. It is essential to the patient's ongoing care, as well as a defense in the event your care is called into question. Poor documentation can hurt physician credibility by making good care look bad. Incomplete or inaccurate documentation can make a case difficult to defend even when the care provided was defensible.

Lack of documentation related to vaccination is problematic should the patient suffer an adverse reaction. It is also problematic if a patient is lost to follow-up (e.g., does not return for the second vaccine dose).

Risk Management Recommendations

- If you administer the vaccine to individuals who are not your patients, you will need to create a record, and you may want to maintain these records in a separate filing area specific to the vaccination program.
- For each vaccine you administer, document information required by your local vaccination program.
- Document:
    - Patient allergies, including those to vaccines
    - Your informed consent discussion, including:
        - Patient education, including potential side effects and complications
        - Risks, benefits, and alternatives
        - Patient's decisions
    - Vaccine name, dosage, injection site
    - Manufacturer; lot number
    - The name of the person who administered the vaccine
    - The need for the patient to return for a second dose
    - Instructions given to the patient (e.g., what the patient should expect or look for; how to respond; whom to call)
    - That the patient received the Emergency Use Authorization (EUA) Fact Sheet

Supervision of Unlicensed Staff

If unlicensed staff (e.g., medical assistants, techs) are going to administer injections, make sure they are doing so under your written supervision.

Risk Management Recommendations

- Ensure that staff is trained properly in injection techniques, and document employee competency in personnel files.
- Prior to unlicensed staff performing injections, a physician or other licensed provider should

verify that the vaccination and dose are correct (state law may require such verification); document verification.

Limited Physician-Patient Relationship

Ophthalmologists who set up a site to provide the vaccine to individuals who are not their patients (as opposed to working at another established site) will have additional responsibilities. It is important to avoid creating expectations of continuing care or management of complications, as this will likely be outside the ophthalmologist's scope.

Risk Management Recommendations

- Clearly communicate the limited nature of the relationship to individuals who are not your patients but to whom you are administering the vaccine. Give them instructions about how and where to seek care for complications arising from the vaccine.

Conclusion

Ophthalmologists who do not customarily provide vaccinations should evaluate whether they have the capacity to extend vaccination services to their patients or other community members. They should consider their ability to manage potential emergencies (e.g., allergic reactions) and implement follow-up processes to ensure patients return to obtain their second dose of the vaccine. If an ophthalmology practice determines that it does not have the resources to manage this service, physicians may consider volunteering with other health systems that are registered sites and are accustomed to responding to medical emergencies.

Additional Resources

Sax PE. COVID-19 Vaccine. Frequently Asked Questions. *New England Journal of Medicine*. Available at: https://www.nejm.org/covid-vaccine/faq (Accessed: 1/25/21)

American Medical Association (AMA). COVID-19 Vaccine: FAQs. Available at: https://www.ama-assn.org/system/files/2020-12/covid-19-vaccine-physician-faqs.pdf (Accessed: 1/15/21)

The FDA's Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers) gives information on vaccine administration, safety, storage, informed consent, and reporting adverse events specific to the Pfizer vaccine.

American College of Physicians (ACP). Vaccine Resources. In: COVID-19: An ACP Physician's Guide and Resources (Last Updated: 1/15/21). Available at: https://assets.acponline.org/coronavirus/scormcontent/#/lessons/kwJbUTKXK1SULXbRPFsZbpMAMKMMXgV9 (Accessed: 1/15/21)

Centers for Disease Control and Prevention (CDC). Different Vaccines. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html (Updated January 15, 2021). (Accessed: 1/20/21)

For CDC information specifically addressing the Pfizer-BioNTech COVID-19 vaccine and Moderna vaccine: Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States.(Accessed: 2/2/21)

Centers for Disease Control and Prevention (CDC). Prevaccination Checklist for COVID-19 Vaccines. Available at: https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf (Accessed: 1/20/21)

Centers for Disease Control and Prevention (CDC). Vaccines and Immunizations. Managing Anaphylaxis. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fanaphylaxis-management.html (Accessed: 1/26/21)