

COMMONWEALTH of VIRGINIA

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February 10, 2021

The information provided in this Memo relates to human rights regulations and the specific scenarios addressed. The information is regarding COVID-19 vaccinations relative to provider policies, a provider's obligation to offer the vaccine and obtain consent, and issues of vaccine administration over individual objection. The guidance provided in this Memo should not be construed as legal advice. Providers are urged to consult with their own legal counsel if they have questions related to the legal issues surrounding COVID-19 and vaccination.

Provider Policies

Providers can update their policies to include information about the COVID-19 vaccine. Provider policies may address admission and exclusionary criteria. Providers should consult with their own legal counsel regarding any policy that mandates individuals receive the COVID-19 vaccine to ensure that it complies with state and federal law. Any policy change that impacts the rights of individuals receiving services will require review by OHR in accordance with 12VAC35-115-260(A)(9).

Please Note: In addition to review by OHR, the DBHDS Office of Licensing will be checking to ensure that providers have followed their own policies and procedures related to screening, admission, and discharge during annual inspections and investigations, as necessary.

Provider Considerations for COVID-19 Vaccination

Based on the scientific evidence currently available, the COVID-19 vaccine is a medical treatment that may prevent possible imminent or irreversible physical harm, such as hospitalization and/or death, related to being infected with COVID-19. Providers should, in advance of offering the COVID-19 vaccine to individuals, secure consent from the individual or her substitute decision-maker prior to administering the COVID-19 vaccine.

Providers should have a plan for supporting the individual during the administration of the vaccine, to include prior education and discussions with the individual and Authorized Representative, (if applicable), about day-of supports. Support to the individual during the vaccination process may include hands-on support such as hand or arm holding, and should consider the possibility for prior communication with the administering technician to ensure as smooth a process as possible. A hands-on support with the agreement of the individual that doesn't prevent him from moving his body is not considered a restraint.

Consent for COVID-19 vaccination

Pursuant to 12VAC35-115-70(A)(2), an individual has the right to give or not give informed consent to receive or participate in treatment or services that pose a risk of harm greater than ordinarily encountered in daily life. An individual who has capacity can refuse to take a COVID-19 vaccine. Any forms used by the provider to obtain consent from an individual with capacity for the COVID-19 vaccine should be in a manner, format and, language most frequently understood by the individual and clarify that the choice to receive the vaccine is the individual's alone.

If an individual has a properly appointed substitute decision-maker, that person has the authority to consent or refuse the COVID-19 vaccine on behalf of the individual who lacks the capacity to consent.

When the capacity of an individual to consent to treatment or services is in doubt, the provider shall obtain an evaluation conducted by or under the supervision of a licensed professional who is not directly involved with the individual to determine whether the individual has capacity to consent. Capacity evaluations shall be conducted in accordance with accepted standards of professional practice and shall indicate the specific type of decision(s) for which the individual's capacity is being evaluated (e.g., medical), and shall indicate what specific type of decision the individual has or does not have the capacity to make. Capacity evaluations shall address the type of supports that might be used to increase the individual's decision-making capabilities [12VAC35-115-145].

When it is determined that an individual lacks the capacity to consent, the provider shall recognize and obtain consent or authorization for those decisions for which the individual lacks capacity from a properly appointed substitute decision-maker to include, first an attorney-in-fact, health care agent, or legal guardian. If none of these are available, the provider director shall designate an Authorized Representative (AR) in the following order of priority unless, from all information available to the director, another person in a lower priority is clearly better qualified: a spouse; an adult child; a parent; an adult brother or sister; or any other relative of the individual [12VAC35-115-146]. If an individual has a properly appointed substitute decision-maker, that person has the authority to consent to the COVID-19 vaccine.

Unresponsive AR:

Providers should have clear documentation demonstrating attempts at written and verbal communication with individuals and ARs about the provider's vaccination plan. This communication should include the date of the vaccine offering, the location and process by which the vaccine will be administered, associated costs or expectations, and the process and timelines for obtaining informed consent.

When the substitute decision-maker for an individual who lacks capacity is not available or unreachable, as with any other type of treatment requiring informed consent, the COVID-19 vaccine may only be administered if the situation rises to the level of an emergency and it is provided in accordance with the provisions found at 12VAC35-115-70(B)(5), or in accordance with a court order or other provisions of law that authorize such treatment.

If an individual objects at any time to the appointment of a specific person as his AR or any decision for which consent or authorization is required and has been given by his AR, other than a legal guardian, he may ask the LHRC to decide whether his capacity was properly evaluated, the authorized representative was properly appointed, or his AR's decision was made based on the individual's basic values and any preferences previously expressed by the individual to the extent that they are known, and if unknown or unclear in the individual's best interests. [12VAC35-115-200].

Consent has been received but the individual objects:

If the individual is not physically resisting, there is no issue; the medication may be administered pursuant to the AR or other properly appointed substitute decision-maker's consent. If the individual is physically resisting and it becomes necessary to put hands on the individual to administer the COVID-19 vaccine, this becomes a restraint. In accordance with

the human rights regulations and other laws, restraint is only permissible when necessary to ensure the "immediate physical safety of the patient, a staff member, or others," which is a determination to be made solely by treating professionals in the exercise of professional judgement based on an individualized assessment. All requirements for utilization of emergency restraint (individualized assessment, no standing orders, exploration of least restrictive alternatives, documentation requirements, etc., per 12VAC35-115-110) must be met. The clinical decision to utilize restraint must be person centered and must take into account any documented contraindications to restraint for that individual.

If you have any additional questions related to the effects of COVID-19, please visit the new DBHDS webpage created to help with questions associated with COVID-19. The new page can be found at the following link: <u>www.dbhds.virginia.gov/covid19</u>. If you have a question that is not yet in the FAQ document, please use the e-mail address provided on the webpage linked above to submit your concerns. Our staff will research your question and their responses will be added to the FAQ document on a rolling basis to benefit others who may have similar questions. If you have legal questions, please consult your attorney.

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