

2023 Required VFC Education

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NORTH  
Dakota

Health & Human Services

Be Legendary.

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VFC Program Only

- The program requirements discussed today only impact the VFC program. COVID-19 vaccine recommendations and program requirements may differ. For specific programmatic questions on COVID-19 vaccine please consult the Adult Vaccine Program at [covidvaccine@nd.gov](mailto:covidvaccine@nd.gov).

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Overview

Enrollment Process

Eligibility and Vaccines Covered

Billing

Borrow/Return

VFC Agreement

Storage and Handling

NDIS Update

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## Acronyms/Terminology

- VFC – Vaccines for Children
- 317 – Vaccine budget that allows for special vaccination programs
- CDC – Centers for Disease Control and Prevention
- NDIIS – North Dakota Immunization Information System
- HHS – North Dakota Department of Health and Human Services

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## Enrollment Process

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## Enrollment process

- Vaccine Management Template, Borrow/Return forms and Vaccine Coverage Tables are always available on our website
- 2023 Vaccine Management Policy is in the process of being printed and will be mailed to each VFC enrolled facility by the end of the month.
  - After initial mailing additional copies will be available for order.
- Email with enrollment survey and VFC provider profile later this week.

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## Enrollment process

- Education
  - Surprise – you are part of the way through the education requirement!
  - Lunch and Learn posttest satisfies education requirement
  - Posttest must be completed and passed by AT LEAST two people from each VFC enrolled facility
- Online survey: [www.hhs.nd.gov/immunizations/providers](http://www.hhs.nd.gov/immunizations/providers)
  - Update contact information
  - Storage and handling information
  - Medical Director signature (can be sent electronically to vaccine@nd.gov)
- **Due on or before Friday, March 3rd**

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Program Eligibility and Vaccines Covered

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## VFC Program Eligibility

- Individuals who are 18 years and younger who are:
  - Uninsured
  - Underinsured – has private health insurance but it does not cover vaccines.
  - American Indian
  - Medicaid enrolled/eligible
- Through 19<sup>th</sup> birthday
- Do not need to prove tribal membership

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### 317 Program Eligibility

#### • Un/underinsured adults:

- Td/Tdap
- MCV4
- MMR
- PPSV23
  - 19 – 64 year old with a high-risk condition
- Pneumococcal Conjugate (PCV15 and PCV20)
  - 19 – 64 year old with a high-risk condition

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### 317 Program Eligibility, cont.

#### • Un/underinsured adults:

- HPV
  - Medicaid adults should receive private vaccine (no longer an age gap in Medicaid coverage for adults)
  - 19 – 45 years of age (2022 change)
- Influenza
  - Available for all providers to prebook and order

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### 317 Program Eligibility, cont.

#### • Un/underinsured adults:

- Adult Hepatitis A and B
  - Not available to adults whose sole purpose of vaccination is for travel or employment.
  - Should be prioritized for those at risk of infection such as drug users and people experiencing homelessness.
    - For a complete list of risk factors please consult the vaccine coverage table at: [www.hhs.nd.gov/immunizations/providers](http://www.hhs.nd.gov/immunizations/providers)

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### 317 Program Eligibility, cont.

- All infants born in a North Dakota birthing facility receive state-supplied hepatitis B vaccine, regardless of insurance status.
- Underinsured patients seen at private healthcare facilities
  - Federally Qualified Health Centers (FQHCs), Rural Health Centers (RHCs) and deputized local public health units use VFC vaccine for underinsured patients.

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### Common Eligibility Misconceptions

- Out of network
  - Not VFC eligible
- High deductible
  - Not VFC eligible
- Christian based cost sharing plan
  - VFC eligible – not considered insurance
  - Questionable insurance? – Insurance commissioner's office
- Out of state Medicaid
  - VFC Eligible but patient will have to pay out of pocket for VFC administration fee

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### Patient Eligibility Screening

- Every patient must be screened at every immunization encounter.
- Patient insurance changes constantly and it is important for several reasons to make sure the clinic has the most up-to-date insurance information.
- Proof of screening will be reviewed at every VFC compliance site visit.
  - Example: If the patient's eligibility is " Medicaid" the clinic will need to show proof of Medicaid number or card and that the screening information was checked on the date of the immunization encounter.

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### Billing for VFC Vaccine

- Never bill for the cost of the vaccine
  - Vaccine provided to clinics at no charge
- Cannot bill more than \$20.99
- Per dose
- Cannot turn over to collections or turn patient away due to the inability to pay for the administration fee
- Must accept Medicaid reimbursement rate

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**Billing**

- Clinics must bill at the time of service or:
  - Bill within 90 days of service AND
  - Bill patient only once
  - Patient cannot be sent to collections for the administration fee (this is not new and has always been a part of the VFC program).
  - Unpaid administration fees must be waived by the clinic/health system.
  - Patients cannot be turned away or referred if they are unable to pay the administration fee.
- These billing requirements are only applicable for the vaccine administration fee, all other clinic/lab/hospital fees are outside of the scope of the VFC program.

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### Borrow and Return

- Any time a vaccine funding source (VFC/State vs. Private) is given to someone that doesn't match their eligibility a borrow is created in the NDIIS. If a balance already exists for that vaccine a return is created in NDIIS.
  - Example: Private vaccine given to uninsured child.
  - Example: VFC vaccine given to an insured child.
- All borrow and returns should be documented on a borrow and return form AND in NDIIS.
  - Borrow/Return form available here: [www.hhs.nd.gov/health/diseases-conditions-and-immunization/immunizations/immunization-resources](http://www.hhs.nd.gov/health/diseases-conditions-and-immunization/immunizations/immunization-resources)



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## Borrow/Return Documentation

- If you are part of a health system work with IT, billing and administration to determine the most appropriate way to document borrow/returns in your EMR.
  - Some health systems must document according to how the patient should be billed and not how the dose was administered.
  - In this situation the data entry must be corrected in NDIIS so a borrow or return occurs.

## Borrow/Return Reports in NDIIS

[illegible]

- **NDIIS Borrow/Return Balance Report**
  - Shows doses owed to state and doses owed to private.
  - All doses ever borrowed or returned, no date range option.

## Borrow/Return Reports in NDIIS

- NDIIS Borrow/Return Detailed Report

- Shows patient information for doses involved in a borrow or return.
- Providers can run for a specific date range or look at all borrows/returns.
- A good tool for catching unreported borrowing or data entry mistakes.
- All doses on this report must be documented on a borrow/return form.

[illegible]

## Follow all ACIP Recommendations

- Providers are required to follow immunization schedules, dosage and contraindications established by the ACIP unless:
  - In the provider's medical judgement, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;
  - The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
  - Example: A provider office that is not administering hepatitis A vaccine to any of their patients would be in violation of the VFC program requirements.

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## VFC Record Retention

- All records that pertain to the VFC program must be kept on hand for at least three years. These records include, but are not limited to:
  - Paper temperature logs
  - Electronic data logger temperature logs
  - Vaccine Packing Slips
  - VFC screening and eligibility documentation
- Immunization information in a patient's medical chart should be held at least as long as the VFC requirement (3 years) but may need to be kept longer according to the clinic's medical record retention rule.

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## Vaccine Information Statements

- Federal law to give a VIS with each and every vaccination, regardless of age of patient or participation in the VFC program.
- Anytime there is an update to a VIS, all clinic contacts will receive the update via the immunization unit listserv.
- When in doubt consult the CDC [website](#).
- Providers are not required to keep large printed inventories of VISs on hand.
  - A paper free option: providers can have a binder of VISs in their office for parents to review prior to vaccination.
  - Parents and patients must be given the option to take home printed copies of the VISs.
  - Print directly from CDC website or EMR each time VIS is needed.
  - Both options save on printing and reduce wastage when updates to VISs are made.

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## Vaccine Adverse Event Reporting System

- VAERS is a database that is used to analyze vaccine adverse events.
- Anyone can report to VAERS. This includes health departments, healthcare providers, patients and vaccine manufacturers.
- This also means that the same adverse event could be reported more than once or events that most would not deem related to a vaccine (car accident following immunization) can be reported as such.
- Report all VAERS to their website: <https://vaers.hhs.gov/>
- Icon in NDIIS



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## Offering All Routine and Non-Routine Vaccines

- All enrolled VFC facilities are required to carry ALL routinely recommended vaccines.
  - Certain exceptions can apply but must be approved by the HHS Immunization Unit.
- Non-routinely recommended (PPSV23 and Men B) vaccines must be made available to all VFC eligible patients who either request them or are recommended to receive them based on a high-risk condition.
  - VFC is an entitlement program, so therefore anyone who is eligible is entitled to that vaccine.
  - Providers are encouraged to keep both PPSV23 and Men B on hand at all times, however it would be acceptable to order at the time the dose is needed.
- Td and PPSV23 are available for order in 1-dose increments.
- DT being discontinued.

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## ND – Vaccine Brand Choices

- ND has a brand choice law, meaning the Immunization Unit is required to offer all vaccines that are offered by the Federal Contract.
- As new vaccines are made available, they are added to the NDIIS to allow for facility ordering.
- The HHS Immunization Unit will never express a brand preference and facilities are able to choose which vaccine brands and presentations they carry.

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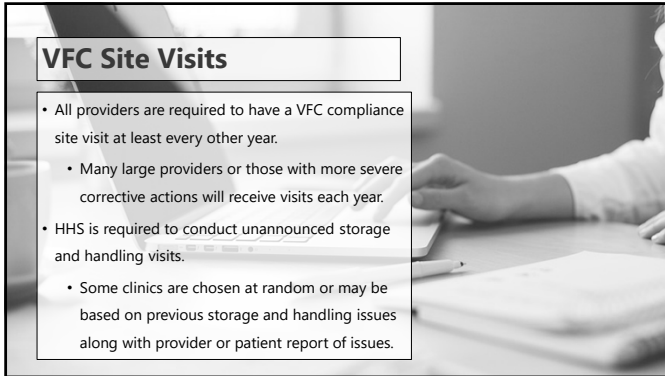
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### VFC Site Visits

- All providers are required to have a VFC compliance site visit at least every other year.
  - Many large providers or those with more severe corrective actions will receive visits each year.
- HHS is required to conduct unannounced storage and handling visits.
  - Some clinics are chosen at random or may be based on previous storage and handling issues along with provider or patient report of issues.

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### VFC Site Visit Overview

- There are many areas that are covered during a VFC compliance site visit but some of the important and often incorrect areas include:
  - Borrow/return documentation
  - Doses owed to the state that have not yet been repaid
  - Correct storage and handling procedures
  - Review of temperature logs
  - Chart Audit
  - VIS publication dates
  - Current calibrated data loggers
  - Current calibrated back-up data loggers
  - Vaccine Management Template complete and up-to-date

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### Virtual Visits to Discontinue

- The federal VFC program has made the determination that virtual VFC visits will be discontinued effective July 1, 2023.
  - After this date only in-person VFC visits will be offered.
  - Virtual VFC visits may continue until June 30<sup>th</sup>.
  - IQIP will remain having both an in-person or virtual option.

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## Vaccine Loss Policy

- There are certain thresholds in which providers will be required to pay back VFC or state-supplied vaccines on a dose for dose basis.
- Exact situations found in the vaccine loss policy which is part of each year's Vaccine Management Policy.
- Common reasons for repayment:
  - More than 20 doses of a particular vaccine expire in a 30-day time period
  - Storage and handling mishaps that are deemed to be the provider's fault
  - Not taking appropriate actions when a temperature excursion happens

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## Vaccine Storage and Handling



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## Importance of Storage and Handling

- Storage and handling can be a time consuming and costly endeavor!
- However, if you think that one box of HPV9 vaccine purchased privately is over \$2,000 and most providers store on average between \$30,000 – \$40,000 worth of vaccine in their refrigerators at any given time.
- VFC providers in North Dakota receive anywhere up to \$800,000 per facility worth of VFC vaccine in any given year!
- Without good storage and handling, facilities can lose thousands of dollars, patients can receive sub optimal vaccines and may not be protected against very serious, even fatal disease.

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## Vaccine Storage and Handling

- All vaccines, except varicella, MMR®II, and MMRV must be stored in the refrigerator at **36°F - 46°F (2 - 8°C)**.
  - Optimal refrigerator temperatures are **39°F - 42°F (4 - 6°C)**.
- MMRV and varicella vaccine must be stored in the freezer at **-58°F to 5°F (-50°C to -15°C)**.
  - Optimal freezer temperatures are **3°F or colder ( $\leq -17^{\circ}\text{C}$ )**
- MMR®II can be stored in the refrigerator or freezer
  - Priorix® MMR vaccine **MUST** be stored in the refrigerator only.



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## Data Loggers

- All storage units that contain VFC or state-supplied vaccine must use a continuous recording data logger.
- Back-up data loggers are also required in the event that the data logger would malfunction or quit working.
  - Required even if facility has a built-in temperature monitoring system.
- Vaccine orders will not be approved without a data logger temperature chart.
  - Any provider that does not submit monthly data logger temperature charts will be contacted by the Immunization Program and will not be able to order until they have been submitted.

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## Data Logger Requirements

- The following are additional recommended characteristics for these devices that are required of all data loggers:
  - Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol)
  - Alarm for out-of-range temperatures
  - Current, minimum, and maximum temperature indicator
  - Low-battery indicator
  - Accuracy of  $\pm 0.5^{\circ}\text{C}$  ( $\pm 1^{\circ}\text{F}$ )
  - Memory storage for at least 4,000 readings
  - Recommended maximum logging interval (or reading rate) of every 30 minutes that can be programmed by the user

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## Temperature Charts

- Paper temperature logs may still be required to be used at clinics.
  - If a clinic's data logger can track date, time and staff initials of temperature checks, paper logs may be discontinued.
- Paper logs should be kept at clinic and will be reviewed at VFC compliance site visits.
  - Must be saved for three years. Can be discarded after that.
- Electronic data logger temperature charts should be emailed monthly (or sooner with temperature excursions) to [dohtemplogs@nd.gov](mailto:dohtemplogs@nd.gov).

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## Min/Max Temperature Requirement

- All providers are required to document minimum/ maximum temperatures once daily.
  - Preferably at the start of the clinic day.
- This requirement replaces the previous twice daily temperature checks.
  - Providers can continue to check temperatures twice daily and record if that is their preference.
  - Clinic staff should visually check temperatures each time a vaccine storage unit is entered to ensure that correct temperatures are being maintained throughout the day.

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## Storage and temperature monitoring equipment

- To fully ensure the safety of vaccines, the following equipment is recommended:
  - Stand-alone refrigerator(s) with enough space to accommodate your maximum inventory without crowding.
  - Stand-alone freezers with enough space to accommodate your maximum inventory without crowding.
- Dormitory units must NEVER be used to store state-supplied or VFC vaccine.
  - Regardless of reason or duration.

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## Vaccine storage and handling

- Out-of-range temperature: what do I do?
  - Vaccine manufacturers should be contacted first to determine vaccine viability.
  - Do NOT assume that vaccine is not viable
  - Do NOT discard any vaccine until the NDDoH has been notified
  - Label the vaccine as "DO NOT USE"
- All actions must be recorded and submitted monthly with temperature logs.
- Even one out-of-range temperature, especially on the cold side, may result in the need for revaccination!

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No Apologies

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## Do not disconnect signs

- Do not disconnect and circuit breaker signs are required for all outlets and circuit breakers connected to storage units with VFC or state-supplied vaccines.
- May seem obvious to clinical staff but in a healthcare facility many other staff involved with storage units, i.e., weekend maintenance or cleaning staff.



State of North Dakota | Health & Human Services  
No Apologies

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## Vaccine transport

- Vaccine transport is discouraged whenever possible.
- If providers must transport vaccine, data loggers must be used at all times.
  - Transport temperature charts must be submitted to the immunization program anytime VFC vaccine is transported.
  - Temperatures should be checked and documented every *HOUR* (2023 change to align with CDC recommendations).
- VFC or state-supplied vaccine must be transported in qualified coolers or packouts.
- Never leave vaccine unattended in a car for long periods of time, and never store in a trunk.
- All vaccines transfers (between providers) must be approved by the immunization program.
- All non-COVID Vaccine should never be stored in a transport cooler for more than 8 hours.
- Frozen vaccine must be transported in a frozen transport cooler, cannot use dry ice or transport refrigerator.

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## Vaccine ordering

- We ask that providers only order once per calendar month.
  - Please contact the Immunization Unit ([vaccine@nd.gov](mailto:vaccine@nd.gov)) prior to placing additional orders.
- Vaccine orders are submitted to the HHS Immunization Unit via NDIIS by providers for review and approval.
  - Order minimum – 1 month
  - Order maximum – 3 months

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## Distribution System

- Non-frozen vaccine is shipped directly to your clinic from centralized distributor (McKesson).
  - Vaccines are generally shipped on Monday, Tuesday and Wednesdays.
  - Flu will be shipped separately and is generally overnighted.
- Varicella and MMRV vaccines are shipped directly from Merck.
  - Varicella and MMRV can ship any day Monday through Friday.
- It is incredibly important to keep the NDIIS up-to-date with accurate address, contact and business hour information each time a vaccine order is placed.

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## Distribution System (cont.)

- **DO NOT** ship viable vaccine to McKesson.
- **DO NOT** ship viable or non-viable vaccine to the NDDoH.
- **DO NOT** contact UPS for vaccine returns or your facility may be charged!

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## Returns Vs. Wastages

- Vaccine Return: nonviable vaccine that needs to be returned to McKesson because it was expired, was spoiled because of a temperature excursion or because of a vaccine recall.
  - Multi-dose vials (MDV) can only be returned if no doses have been drawn from the vial. Partially used MDVs must be documented as wasted vaccine.
  - Example: Expired vaccine, delivered non-viable etc.
- Vaccine Wastage: nonviable vaccine that is not able to be returned to McKesson. This includes broken vaccine vials or syringes, vaccine drawn into a syringe but not administered, lost or unaccounted for vaccine and partially used multi-dose vials.
  - Example: Open multi-dose vials, broken vials etc.

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## Vaccine Returns and Wastages

- All vaccine returns and wastages must be entered into NDIIS and returned to McKesson within six months of becoming nonviable.
- Once the return has been submitted in the NDIIS, the primary contact will receive an email 1-2 business days later letting them know that their packing slip is ready to be printed.
- The provider should go back into the submitted return and print the packing slip.
- By submitting the return in NDIIS your pre-paid shipping label has been requested from McKesson and should be received in the mail 1-3 weeks later or via email within a few business days.
- If you do not receive your packing slip or shipping label, please contact a member of the immunization program.
  - Allow 2-3 business days before contacting.

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## Recent NDIIS Changes

- Lot numbers are no longer a drop down
  - No more dummy doses!
  - Accurate data entry and inventory control are ESSENTIAL
- Borrow/Return reports removed COVID-19 vaccine from reports.
  - Once COVID-19 vaccine is available on the private market the vaccine will reappear on this report.
  - Also alphabetized again!
- Patient based doses administered report
  - Allows providers to pull patient information for a certain vaccine or time period

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## Commercialization of COVID-19 Vaccine

- Later in 2023 COVID-19 vaccine will go from being fully supplied by the Federal Government to the private market.
  - Will need to maintain private and VFC inventory for COVID-19 vaccine
  - May require EMR changes

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## Post-Test

- Required VFC Education Survey: [https://ndhealth.co1.qualtrics.com/jfe/form/SV\\_ekPTnDZKA9pmvFc](https://ndhealth.co1.qualtrics.com/jfe/form/SV_ekPTnDZKA9pmvFc)
- Successfully complete the five-question post-test to receive your certificate for nursing credit and to complete the VFC enrollment requirement
  - Certificates will be an email from [noreply@qemailserver.com](mailto:noreply@qemailserver.com). If you don't receive your certificate within a few minutes of passing the posttest, please check your junk mail and check with IT.
  - If you still cannot retrieve the certificate, please email Miranda at [mlbaumgartner@nd.gov](mailto:mlbaumgartner@nd.gov)
- This presentation will be posted to our website: [www.hhs.nd.gov/immunizations/providers](http://www.hhs.nd.gov/immunizations/providers)

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