STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

GRETCHEN WHITMER
GOVERNOR

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DIRECTOR

MEMORANDUM

DATE: March 19, 2020

TO: Michigan Local Health Departments

FROM: MDHHS Division of Immunization

SUBJECT: **COVID-19 Guidance**

We wanted to keep each of the Local Health Departments (LHDs) informed about the happenings within the Division of Immunization. As we all manage the response to Coronavirus (COVID-19) together we want to express our support of all of you. We thought we would recap what the guidance is for the programs within the Division of Immunization, along with guidance from the Centers for Disease Control and Prevention (CDC). This way everyone has a clear understanding of the guidance we are putting forth as we work to meet the needs of the public during the COVID-19 outbreak.

You will find there is guidance on certain tasks that must continue, as indicated by CDC providing additional guidance. We want to acknowledge that we are aware several LHD clinics have needed to transition staff to other tasks, limiting the ability to perform immunization tasks as normal. If your LHD is experiencing such limitations in staff capacity for tasks identified in this plan – please notify your MDHHS Field Representative. We want to ensure support for your staff with discussion on alternative approaches, backup plans, and troubleshooting whenever feasible.

NEW FAX LINE FOR TEMPORARY USE: LHDs who need to send faxes, please use this eFax line until further notice: 517-763-0370. This is different from our typical fax line. Alternatively, it is preferred that documents are scanned and emailed to the appropriate program staff whenever feasible.

1. **Vaccines for Children (VFC)**

   a) **Temporary suspension of ALL on-site VFC and on-site IQIP visits in Michigan**.
   - The CDC has also provided notification that nationwide, these visits must be suspended immediately**:** For VFC, this includes compliance visits, enrollment visits, storage and handling visits. For IQIP, this includes any in-person visit (i.e., initial or follow-up).
   - **Length of suspension:** This suspension is tentatively expected to last until May 1st. However, this will be continuously re-assessed, and any changes to this timeframe will be communicated as soon as available. This will be communicated both to CDC and Michigan site reviewer/consultants.

   b) Ensuring storage and handling of vaccine is maintained: With suspension of on-site visits, CDC has provided additional guidance on expectations for ensuring storage and handling. These are as follows:

- All VFC Providers in Michigan (and other public vaccine providers – 317, state) must submit temperature logs each month, with documentation of this submission maintained. Michigan requires temperature logs also be submitted and reviewed before orders are approved. These temperatures reviewed, must include all days since the previous order/submission.
- Please ensure receipt and documentation for your respective providers. Contact providers for any technical assistance/follow-up that may arise.
- LHDs must also submit monthly temperature logs to MDHHS VFC staff who maintain documentation of this, and we will provide technical assistance/follow-up as needed.
- Digital data logger (DDL) downloads must be requested and submitted when temp logs indicate temperatures that are out-of-range, missing, or questionable.
- Appropriate follow up on all excursions is required. All temperature excursions must be reported to the LHD and/or MDHHS immediately, with appropriate follow-up.
- Failure to submit monthly temperature logs or additional documentation requested from LHD/MDHHS to ensure storage and handling - may result in ordering suspension.
- Technical assistance on storage and handling is performed by LHD staff, MDHHS staff, and detailed guidance is available for providers to review online: Within the VFC Provider Manual (pg. 45), as well as the MDHHS Guidance on Responding to Temperature Excursions. MDHHS VFC staff are available to support LHDs for case-by-case review when atypical concerns arise. This support will be maintained.
- **Providers due/overdue this quarter or displaying concerns** – Attached is a spreadsheet of providers overdue or due for a visit by the end of the cycle. At your discretion – you may request that these providers, as well as providers who display storage and handling concerns, may be asked for additional documentation requested as a "Spot Check" for S&H assurance. This request would be done remotely and would not require an on-site visit. For example, review of temperature logs and/or training documentation can be requested prior to order approval. Other requests could include photos of storage and handling (picture of storage units, DDL placement, certificates of calibration).
    - These must be documented in PEAR via "VFC Contact" in PEAR. CDC may retrospectively count these activities towards awardee site visit requirements.
- Emergency vaccine transport will be handled as normal operation (indicated in the VFC Provider Manual and MDHHS Transport Guidance).

c) VFC Provider Enrollment

- Most typical enrollment activities are still required as normal: Provider agreement, Provider Profile, VFC Annual Training and VIM training, Management and Emergency Plans, etc. Some of these may involve remote training.
- However, on-site enrollment visits are also suspended. Completion of some aspects of the on-site enrollment visit may be performed by an alternative remote approach in assessing storage and handling:
    - For example, photos of storage units, DDL placement, certificates of calibration, "Do Not Unplug" signs, etc.), the LHD must receive prior approval from MDHHS.
    - These can be documented in the Enrollment Visit in PEAR, and progress with "met" or "unmet" as they are reviewed.

- Michigan has four providers in-progress of new enrollment that have NOT YET had an "Enrollment Visit". The four providers who are entered in PEAR and do not have an "Enrollment Visit" documented are the following:
  - 630305: initiated enrollment process 2/4/2020
  - 730102: initiated enrollment process 2/5/2020
  - 840568: initiated enrollment process 3/4/2020
  - 840569: initiated enrollment process 3/16/2020

d) **DEADLINE EXTENDED for VFC Re-enrollment**

- Re-enrollment for VFC providers will be extended by 1 month. All VFC re-enrollments must be at the MDHHS level by COB May 1, 2020.
- We've attached a sample email for you to distribute to providers. As of 3/17/20, there are still 157 providers with incomplete enrollments.
  - We may need providers enrolled should a vaccine be made available for coronavirus.

e) Continued Review and submission of VFC vaccine orders

- Maintaining access to vaccine is critical and must continue; LHD and MDHHS staff must establish a plan to ensure orders are still reviewed and submitted in a timely fashion. These include the elements mentioned above – receipt and review of temperature logs and potentially additional information.
- For LHD VFC vaccine order supporting documents, MDHHS VFC **prefers** that these are **scanned and emailed** directly to MDHHS VFC Staff (Kyle, Darcy, and Maria). However, if you need to utilize faxing, please use the new eFax line: 517-763-0370.
- Special note on school clinics and providers closing:
  - Due to the number of schools and provider offices temporarily closing due to COVID-19, please keep in mind that orders should not be submitted for providers that are currently closed. McKesson should not be asked to **hold** orders. Please work with MDHHS VFC staff to **cancel existing orders for closed providers and resubmit when the site re-opens**.
  - Additionally – for temporary provider closings due to the outbreak, please see the following recommendations:
    - For school clinics, if there is an end of school year or holiday protocol in place, please utilize it in the event of extended closure.
    - If feasible and if you have documentation that the vaccine has been appropriately stored, transport the vaccine to an alternate safe storage location where it can be used by your program.
    - If transport is not desired or feasible, and a DDL is present that can store sufficient data for the closure, leave vaccine in current unit (mark "do not use").
    - Upon reopening, review all DDL data and take action on any temperature excursion, if any, before administering vaccine.
    - When reviewing DDL data it is important to check that complete data are available for all dates and times.
    - If the DDL ultimately did not have enough capacity to record during the period of closure or experienced failures, you will need to consult with the vaccine manufacturer and LHD/MDHHS to determine if the vaccine can be used or should be discarded.

f) **Vaccine Inventory Management (balancing, return/waste, etc.)**
- CDC still expects vaccine accountability be maintained during this time, especially considering suspension of compliance visits. However, we understand that the needs and time commitments of the provider, LHD staff, and MCIR staff for VIM support may vary case-by-case.
- Remote VIM trainings are being explored to support providers, however, some providers may not be capable of these types of venues and may need traditional training performed at a later time.
  - In situations like this, MCIR staff and LHD should assist the provider to accomplish the task at-hand.
- MCIR regional staff are exploring options to support providers with abbreviated, "just-in-time" training for an identified portion of training based on the provider's need in that moment. Communication between the LHD and MCIR staff when such training sessions occur is crucial.

g) Continued VFC Fraud and Abuse monitoring and investigations
- Current Michigan fraud and abuse procedure in place (according to VFC Provider Manual and online VFC Resource Guide); The primary contact for Fraud and Abuse allegations is Maria McGinnis, VFC Coordinator.

h) **VFC follow-up and documentation should continue**
- i.e. PEAR documentation on follow-up action list if reviewer receives communication on completed follow-ups.

i) If you have questions, please contact your field representative and if necessary, the program lead (Maria McGinnis.)

2. Immunization Quality Improvement for Providers (IQIP):

a) **Temporary suspension of Quality Improvement (QI) site visits until further notice.**

b) **IQIP check-ins and follow-ups should continue via phone.**
- Consultants will document check-ins and follow-ups in the IQIP database.
- The 'lost to follow-up' option will remain available and used if an IQIP activity is not able to be completed within the allowed timeframe.

c) If you have questions, please contact your field representative and if necessary, the program lead (Stephanie Sanchez.)

3. Immunization Nurse Education (INE):

a) INE in-services may be performed if you have the means to do so and feel it is appropriate. We understand there are several factors being considered by your LHD and leadership – we support the decision of the LHD regarding any INE in-service.

b) Special note on INEs required by MDHHS: (e.g. required INEs for losses exceeding $1500) These required INEs can be considered **suspended until further notice**.
- If a provider has completed other required tasks for a loss (e.g. replaced all doses, sent any documentation for LHD review if needed such as temp logs, etc.), notify Darcy Wildt about such loss replacement and that MDHHS should consider the loss "completed pending INE", until the INE can be completed.

4. Perinatal Hepatitis B Prevention Program (PHBPP):

a) Reporting all hepatitis B surface antigen (HBsAg)-positive results is important and needs to continue. If LHDs are unable to report cases due to constraints during COVID-19, **REFER** any case to the PHBPP at fineisp@michigan.gov, or 517-335-9443.

b) If you are able to complete the reporting of HBsAg-positive results, here are the steps to follow:

- Report all HBsAg-positive results to the MI Disease Surveillance System (MDSS).
  - Verify pregnancy on all HBsAg-positive women of childbearing age (10 – 60 years of age).
- Babies born to HBsAg-positive women **must** receive hepatitis B (hepB) vaccine and hepatitis B immune globulin (HBIG) within 12 hours of birth (If a follow-up provider is deferring services, such as immunizations, it is **CRITICAL** that we ensure these babies receive the appropriate prophylaxis starting at birth).
  - If HBIG was not given at birth or if baby was under 2,000 grams:
    - The second hepB dose **must be given at 1 month of age** (and not 1-2 months of age).
    - A third dose by 6 months of age.
    - Post-vaccination serology at 9-12 months of age (or 1-2 months after vaccine series if hepB series is delayed).

c) Additional guidance for birthing hospitals will be coming soon.

5. Michigan Care Improvement Registry (MCIR):

a) If you have questions or concerns about MCIR system function, training or reports, please contact your Regional MCIR staff.

b) If you have questions or concerns about assessment, please contact your local field representative.

c) MCIR trainings will be required to be performed remotely (phone or WebEx/GoTo web training) to reduce exposure of MCIR staff in provider offices.

Immunization Clinic Services:

COVID-19 response has varied throughout the State. As the virus is becoming more widespread, we may see more LHDs affected. If you are still conducting clinics within your LHD, here are some measures you may consider:

- Appointment only clinics, no walk-in. This will allow for better screening of incoming patients.
- Spread the appointments out during the day to help avoid waiting together.
- Have patient/family wait in their car. You can text them when to walk down to the clinic. This will limit the number of people at your clinic.

We have heard that some immunization clinics have had to suspend services to meet the response for COVID-19 in their communities. During this time MDHHS supports any LHD decision regarding status of LHD immunization clinics. We are also concerned about individuals who may not receive needed vaccines. Please make efforts to restore immunization services as soon as feasibly possible.

Waiver Education Appointments:
As mentioned under immunization clinic services, we know COVID-19 response has varied throughout the State. If you are supporting immunization waiver education appointments some measures that you can take are:

- No walk-in, appointment only.
- Spread any waiver appointments out through the day to help avoid waiting together.
- Have patient/family wait in their car. You can text them when to walk down to the waiver appointment. This will limit the number of people at your clinic.

Waiver education session request should be minimal at this time of the year in part due to the recent closures of schools. Please make every effort to accommodate requests for waivers. Any changes to the existing process could have long term ramifications to the progress we have made to date. Some sessions may need to be delayed.

Immunization Accreditations:
There is a pause in MLPHAP On-Site Reviews, we are also pausing other MLPHAP processes. These include:

- An extension to the Corrective Plan of Action (CPA) timeline for those health departments who are still in the process of implementing CPAs in response to their On-Site Review. The length of the extension is to-be-determined and will be communicated at a later date.
- Suspension of the Standards Review Committee process.
- Suspension of pre-accreditation visits by field staff.

The suspension is expected to last at least 60 days, but that is to be determined depending on the outbreak.

Spring IAP Reports:

- These are typically sent out beginning of April with an end of April due date (time period covered by the reports will be Oct. 1, 2019 – Mar. 31, 2020).
- We are postponing sending out the IAP Reports until beginning of June. This is the earliest date, and the date could change depending on our current situation with COVID-19.

Upcoming Immunization Meetings:

- **INE Meetings:** In-person meetings have been canceled at this time. The possibility of a webinar has been postponed while we work on COVID-19 tasks.
- **IAP Meetings:** At this time the in-person IAP meetings will be postponed. More information to follow later regarding a potential webinar.
- **INE Orientation:** At this time the INE orientation scheduled for April 9th has been postponed. More information to follow later

Thank you for all you do to protect our Michiganders.

For Michigan information on Coronavirus, visit www.michigan.gov/coronavirus.