Reporting Carbapenemase-Producing Carbapenem-resistant Enterobacteriaceae (CP-CRE) via Electronic Lab Reporting (ELR) to the Michigan Department of Health and Human Services (MDHHS)

The following guidance addresses setup of an ORU_01 message profile for electronic lab reporting (ELR) of Carbapenemase-Producing Carbapenem Resistant *Enterobacteriaceae* (CP-CRE). This guidance only applies to ORU_01 message profiles that conform to the HL7 v2.5.1 standard.

When to Report:
Report any detection of *Klebsiella* spp., *Escherichia coli*, or *Enterobacter* spp. from any clinical specimen that is:

1. Resistant to any carbapenem
    - MIC ≥4 ug/ml for doripenem, imipenem, or meropenem
    - MIC ≥2 ug/ml for ertapenem
    - This guidance requires compliance with current MIC interpretation standards – (M100-S27) for MIC breakpoints, available at http://clsi.org/m100/

And, if known:

2. Positive for carbapenemase production
    - Examples of carbanenemases include *Klebsiella pneumoniae* carbapenemase [KPC], New Delhi metallo-β-lactamase [NDM], Verona integron-encoded metallo-β-lactamase [VIM], imipenemase [IMP] metallo-β-lactamase, OXA-48 carbapenemase, etc.

      Examples of recognized tests include polymerase chain reaction, polymerase chain reaction, metallo-β-lactamase test, modified Hodge test, Carba NP, Neo-Rapid CARB, carbapenem inactivation method (CIM), modified CIM (mCIM), etc.

What to Report in ELR:
CP-CRE ELRs must communicate at least the following information:

1. Organism identified
2. Specimen source(s)
3. The antimicrobial/bactericidal agent being tested
4. The method of testing (K-B, MIC, etc.)
5. Both the actual quantitative results and qualitative interpretations of susceptibility testing. For example, when reporting minimum inhibitory concentration (MIC), results written as both micrograms per milliliter (µg /ml) and a statement of interpretation (i.e., susceptible, intermediate, or resistant) should both be reported within the HL7 message.
    - This qualitative finding may be reporting either as a standardized value in OBX-8 "Abnormal Flags" ('S' [Susceptible], 'I' [Intermediate], or 'R' [Resistant]) or as a unique observation segment that includes SNOMED-coded values in OBX-5, using coded entry (CE) or coded with exception (CWE) data type constructions. See "Important Items," below.

All susceptibility reporting must include clear parent-child relationships to tie susceptibility observations and carbapenemase identification observations to the initial organism identification observation. For example, the parent observation is the identified organism (e.g. *Klebsiella pneumoniae*) and the child observation is the antibiotic susceptibility results.

Parent-child relationships must reflect the following dependencies:

- In following examples, the notation 'OBR|1' is used to represent the *parent* order and 'OBX|X_1' is used to represent the *parent* observation (a.k.a., result; where the subscript references the OBR parent segment on which it is dependent). In reality, this OBX may be any OBX iteration that is tied to the parent OBR, if there are multiple OBXs.
- In the following examples, the notation 'OBR|2' is used to represent the *child* order. Again, the child order could be any OBR segment that is dependent on a previous OBR parent segment; it does not necessarily need to be the second iteration.
- Following this segment identification, all fields are indicated after a dash ('-') and, as needed, components follow the period ('.'). In addition to field and component IDs, all field and component names are also provided.
    - For example, 'OBR|2-29.2 "Parent Number.Filler Assigned Identifier"' represents the second component of the 29th field of the dependent, child OBR segment.
- In the following examples, each requirement is outlined by textual description, a brief mapping table, and example.

Fields that Must Match To Properly Link Parent to Child:

1. OBR|1-2 “Placer Order Number” and OBR|1-3 “Filler Order Number” must match OBR|2-29.1 “Parent Number.Placer Assigned Identifier” and OBR|2-29.2 “Parent Number.Filler Assigned Identifier,” respectively.

Placer and Filler Order Number Dependencies:		
Description	**In Parent**	**Must match Child**
Parent Order Number	OBR|1-2	OBR|2-29.1
Filler Order Number	OBR|1-3	OBR|2-29.2
Example, *OBR 2* *OBR 3* *Parent:* OBR|1|987654|123456|… *OBR 29.1* *OBR 29.2* *Child:* OBR|2|||||||||||||||||||||||||| 987654^123456|…		

Fields that Must Match To Properly Link Parent to Child (cont.):

2. OBX|X_1-3 “Observation Identifier,” OBX|X_1-4 “Observation Sub-ID,” and OBX|X_1-5 “Observation Value” must subsequently be tied to OBR|2-26.1 “Parent Result.Parent Observation Identifier,” OBR|2-26.2 “Parent Result.Parent Observation Sub-Identifier,” and OBR|2-26.3 “Parent Result.Parent Observation Value Descriptor,” respectively.

Parent Observation to Child Order Dependencies:

Description	**In Parent**	**Must match Child**	**Notes**
Observation Identifier	OBX|X_1-3	OBR|2-26.1	All components within the field OBX|X_1-3 ***must*** be included as subcomponents in the component of OBR|2-26.1. Additionally, OBR|2-26.1 must follow a Coded Entry (CE) data type construction only using valid LOINC codes in the 1st sub-component, text in 2nd sub-component, and the literal value of LN in 3rd subcomponent.
Observation Sub-ID	OBX|X_1-4	OBR|2-26.2	
Observation Value	OBX|X_1-5.2	OBR|2-26.3	OBR|2-26.3 must be text only

Example,

OBX 3

Parent: OBX|X_1|CE|61399-2^Klebsiella pneumoniae DNA [Presence] in Unspecified specimen by Probe and target amplification method^LN|ABC9999|260373001^Detected^SCT|…

OBX 4 *OBX 5*

OBR 26.1

Child: OBR|2|||||||||||||||||||||||||61399-2&Klebsiella pneumoniae DNA [Presence] in Unspecified specimen by Probe and target amplification method&LN^ABC9999^Detected|…

OBR 26.2 *OBR 26.3*

Fields that Must Match To Properly Link Parent to Child (cont.):

3. Specimen information (SPM-2 “Specimen ID”, SPM-3 “Parent Specimen ID” [for child SPM segments], SPM-4 “Specimen Type”, and SPM-17 “Specimen Collection Date”) is needed for determining whether the referral is a new or recurrent.

   Particular care should be taken for child specimens that are sourced from a parent specimen – the child SPM segment should reference the appropriate specimen source (SPM-4 “Specimen Type”). For example, when an organism is identified from a culture and that isolate is then used as the specimen type for the subsequent susceptibility testing, the isolate should be referenced in SPM-4. SPM-3 “Specimen Parent ID” in the child SPM segment should also reference in ID from SPM-2 “Specimen ID” in the parent specimen segment.

For child specimens that are sourced from a parent specimen:

Description	**In Parent**	**Must match Child**	**Notes**
Specimen ID	SPM- 2	SPM-3	
Specimen Type		SPM-4	

Example, where first OBR segment represents the identification of *Klebsiella pneumoniae* from a blood specimen and the second, dependent OBR segment could represent subsequent susceptibility testing:

Parent: OBR|1|987654|123456|85761-5^K pneumon DNA Bld Pos Ql Non-probe PCR^LN|…

OBX|X_1|CE|85761-5^K pneumon DNA Bld Pos Ql Non-probe PCR^LN||260373001^Detected^SCT|…

SPM 2

SPM|1|XYZ97531||119297000^Blood Specimen^SCT||||||||||||201707091205|…

Child: OBR|2|…

OBX|X_2|…

SPM 3 *SPM 4*

SPM|1|NOP369258| XYZ97531|429951000124103^Bacterial Isolate Specimen^SCT||||||||||||201707101441|…

Important Items:

- Do not embed results in NTE segments.
- Do not embed notes in OBX segments – reserve OBXs for discrete observations/results.
- The sub_ID in OBX-4 should be used with any repeating LOINC code value that exists in more than one OBX-3 within the same OBR parent group.
    - For example, when testing for susceptibility, each susceptibility test must include both a quantitative value and a qualitative interpretation. If the message is set up to result a full OBX segment for the qualitative interpretation, it will use the same LOINC code value in OBX-3 that is used for the quantitative result OBX segment. This will require use of the OBX sub_ID in OBX-4:

      OBR|2|||56031-8^Doripenem [Susceptibility] by Minimum inhibitory concentration (MIC)^LN||||||||||||||||||||61399-2&Klebsiella pneumoniae DNA [Presence] in Unspecified specimen by Probe and target amplification method&LN^ABC9999^Detected |||987654^123456|…

      OBX|1|SN|56031-8^Doripenem [Susceptibility] by Minimum inhibitory concentration (MIC)^LN|1|=^8|µg/ml|||…

      OBX|2|CE|56031-8^Doripenem [Susceptibility] by Minimum inhibitory concentration (MIC)^LN|2|30714006^Resistant^SCT||||…
- Use only LOINC and SNOMED standards in both order and observation reporting (OBR and OBX, respectively) for all non-numeric values. No local codes, please.
- Use “specific” (a.k.a., non-generic) LOINC codes, paired with SNOMED-coded results. “Specific” LOINC codes should include method description (disk diffusion, broth dilution/MIC, etc.).
- Qualitative interpretations in OBX-5, for both organism detection and qualitative susceptibility interpretation (when reported independently of the quantitative susceptibility values), should be constructed using CE or CWE data types.
- Quantitative results in OBX-5 should be constructed using NM or SN data types; SN is preferred.
- Labs that are testing for carbapenemase production (e.g., Modified Hodge) should report findings as discrete, SNOMED-coded qualitative findings. These should be represented as child linkages to parent organism sub_ID, following all of the same dependency requirements described above. Do not embed phenotypic results in NTE segments.