Record of public comments received on proposed changes to regulations 7 AAC 27.005, .007, .012, .014
Reportable Conditions Update: Reporting by health care provider; Reporting by laboratories; Birth defects registry; Reporting of blood lead test results (Law File Number: JU2017200866)

Comments Received From	Comments	Agency Decisions After Review of Comments	Thought Process
	7 AAC 27.005		
N/A	**No comments received**	N/A	N/A
	7 AAC 27.007		
James Tiesinga, MD ANMC Laboratory Medical Director	**Many tribal programs will require more than one working day to submit certain reports.** The Department proposes allowing providers and laboratories only one working day to make certain reports to the State Epidemiology Center, rather than the five days currently allowed. (Proposed 7 AAC 27.005(b) for providers; proposed 7AAC 27.007(b) for laboratories.) ANMC and other THOs that utilize the CERNER Electronic Health Record platform have the capacity to batch release reportable results to the State Epidemiology Center on a daily schedule. For example, the ANMC Laboratory releases these results daily at 2 a.m. However, it is my understanding that THOs utilizing RPMS, and possibly other platforms such as Athena, do not have this capacity. Rather, they must manually collect results and fax them to the State. A 24-hour deadline for this manual process is, in my opinion, unreasonable considering the significant staffing shortages in rural health programs. A one-day deadline is especially problematic for THOs that utilize manual test kits to perform testing of some reportable conditions such as HIV. Test results generated by these kits must be manually entered ("reported") into the patient's record. For test results that are manually entered, the Joint Commission, which is CMS's deemed-status accrediting entity, instructs that the information should be double-checked and verified by a supervisor or designee, generally within 24 hours. (Joint Commission Laboratory Standard, QSA.02.11.01 EP5; *see* also 42 CFR 493.129l(a)1)	Extend the timeframe of reporting from 1 to 2 working days.	The proposed one-day turn-around for infectious disease reporting was intended to improve timeliness identifying and responding to outbreaks/clusters or uncommon diseases. The state understands that circumstances may preclude meeting this target under all conditions. Adding an extra 24-hours to the reporting period eliminates many of the expressed concerns while still enabling more rapid response. Standard practice when we get a reportable condition is to coordinate with the reporting (ordering) provider *prior* to engaging directly with the patient. This practice will continue regardless of the timeframe of reporting.

	Depending on the level of staffing and workflow of a clinic, in many cases it will be extremely difficult or impossible for THOs to meet both this verification standard and the State reporting requirement all within 24 hours. The risk of such a short State deadline is that THOs may sometimes be compelled to report results before they are verified, which runs the risk that the State will receive false results. Further, many THOs send specimens to an outside referral laboratory for testing, who are then required to report results to State Epi on samples obtained within the state. It is reasonable to assume the referral laboratories are technologically equipped to report results to the State within 24 hours if required to do so. However, the referring THOs may not be able to report those results to the affected patient that quickly. Many THOs do not have an electronic interface with their referral laboratories; if they do, this interface is prone to dysfunction. Where there is no reliable electronic interface, referral laboratories routinely fax their results to the THO. But depending on the clinic's staffing and workflow, and the level and reliability of the technology (e.g., fax machines break with surprising regularity), it may take clinic personnel more than 24 hours to obtain and review a fax, enter the data into the patient's record, and notify the patient. The proposed change to this requirement widens the potential dis-synchrony between the time State Epi receives and acts on notification from the referral laboratory and the time the clinic notifies affected patients. It thus increases the risk that the patient, family, and community will be notified by the State of a positive test result before the THO can notify and counsel the patient about the results and initiate appropriate interventions, a situation that is extremely distressing and confusing to patients and their families. For all these reasons, I urge the Department to reconsider the one-day deadline, at least for providers and laboratories		

	that are located in rural areas, or that lack advanced EHRs and reliable electronic interfaces with referral laboratories. For such providers, a three-day deadline would better balance the interests at stake, in my view. It would accommodate the Department's legitimate need for more immediate information; recognize the real-life staffing, technology, and other challenges faced by many THOs; allow reporters to verify information before they submit it to the State; and help ensure that affected patients are first notified and counseled about their condition by their own health care providers.		
James Tiesinga, MD ANMC Laboratory Medical Director	**Reactive HIV screening tests, and negative confirmatory HIV test results, should not be required to be reported.** Current regulations sensibly require laboratories to report only *positive* test results that *confirm* HIV infection. The Department now proposes changing that, by requiring laboratories to report all reactive HIV *screening* tests - despite their rate of false positive results that may approach or even exceed 1 % - as well as both positive and *negative* confirmatory test results. (Proposed 7 AAC 27.007(b (20)(A).) The ANMC Laboratory uses the best HIV screening test on the market, yet every year we identify 5 - 10 patients who initially test false positive on this methodology. This false positive rate mandates confirmatory testing. Until there is a confirmatory test result, a laboratory cannot responsibly determine whether HIV is suspected or exists. Laboratories should not be required to report such inconclusive and unreliable screening test results, nor should they be required to report patients who are determined, upon confirmation, NOT to be infected with HIV. Indeed, the proposed requirement conflicts with federal CUA regulations, which require Laboratory Medical Directors to ensure the quality, accuracy, and reliability of methodologies and interpretation of test results performed	No change.	The reporting of reactive HIV screening tests and subsequent confirmation tests (positive and negative) is within the scope of the current regulations. A reactive screening test result meets the definition of a "suspect case", which is already reportable by law; this revision to the law clarifies that. For HIV, it is important that all tests in the HIV testing algorithm are reported in order to determine the HIV status of patients with reactive screening tests. Because confirmatory tests are often performed at a different laboratory than the original screening test, the performing laboratory may not know that the confirmatory testing is associated with a positive screening test. The provision to report negative confirmatory tests that follow reactive screening tests is necessary to understand the ultimate disease status. Having that complete picture allows us to assure that patients are promptly informed of their true disease status and to assure that our surveillance data are accurate.

	under the Director's CLIA license. (42 CFR 493.1407(e) and 42 CFR 493.1445(e).) Under these standards, Laboratories should not report screening test results they consider to be unreliable, or that confirmatory testing shows to be inaccurate -- yet that is exactly what the State's proposed change would require them to do. The State should not adopt a requirement that conflicts with a federal one, and laboratories should not be forced to choose between conflicting state and federal requirements. Further, because of the rate of false positive results obtained from HIV screening kits, some THOs choose not to report to their patients the results of HIV screening tests; rather, they report only results obtained from HIV confirmatory testing. They do this to protect patients from miscommunication, misunderstanding, and needless fear and distress. In my view, requiring laboratories to report reactive screening test results and negative confirmatory test results to the State interferes with the providers' professional judgment not to report preliminary or discredited results to their patients, and risks a pointless violation of the patients' privacy. For these reasons, the proposed change is misguided, and in my view would serve no legitimate public health purpose. I urge the Department to keep the HIV reporting requirement as it is in current law.		As we reported in the HIV *Bulletin* on false positive HIV screening tests, there have been several occasions where patients were told by their provider that they were HIV-infected based on a positive screening test when additional tests were pending. The *Bulletin* is available at: http://epibulletins.dhss.alaska.gov/Document/Display?DocumentId=1952 Finally, it is not our practice to contact patients directly without coordinating with the ordering provider, and we work closely with providers to understand the testing algorithm and interpret results.
James Tiesinga, MD ANMC Laboratory Medical Director	**Genotype results and associated HIV nucleotide sequence data are not used to diagnose reportable diseases and should not be required to be reported.** The Department proposes requiring laboratories to report "genotype results and associated HIV nucleotide sequence data" to the State. These data are generally not used for diagnostic purposes, except very rarely, when confirmatory test results are ambiguous. They are thus not pertinent to the stated purpose of the regulations as described in the Public Notice, which is to ensure the State receives timely notice of	No change.	The purpose of making genotype sequence data reportable is to conduct molecular surveillance and detect transmission clusters, which, in turn, allows for timely public health intervention and response. This information informs and expedites surveillance and response and is not used for other purposes. Should a specific study be proposed, the state would, of course, follow standard IRB processes.

	discovered or suspected cases of certain health conditions and diseases, and to otherwise deal with "the monitoring and control of diseases of public health importance." The proposed requirement is inappropriate and has no place in these regulations. If the State is interested in obtaining this information for *other* purposes, such as epidemiological research, it should be transparent about that interest, and it should not try to satisfy it through these required-report regulations. Rather, any such research effort should be carefully considered, structured, and explained by the Department to potential research subjects, and data should be collected, stored, and utilized in a way that protects patient rights and complies with applicable federal, state, and ethical standards for such research. Indeed, as I understand it, although the Department may "request information from ... health care providers that identify ... characteristics of individuals with reportable diseases or other conditions of public health importance," (AS 18. l 5.360(b)), it can only *require* providers to report data on suspected or confirmed cases (AS 18.05.042).		The sequence data come from reference labs; only LabCorp, Quest and Mayo are currently performing genotype testing on Alaska clinical specimens. Adding this to regulations enables Alaska to meet CDC requirements and receive grant funding without requiring reporting from, or placing a burden on, Alaska facilities. Since the late 1980s, CDC has formally partnered with state and local health departments to conduct HIV surveillance and expand the impact and reach of HIV prevention in affected communities. It is important that state and local health departments, tribal governments and/or tribally designated organizations, community-based organizations (CBOs), and health care providers focus on preventing new infections by reducing undiagnosed HIV infections and ensuring that comprehensive services promoting linkage to and engagement in HIV medical care are made available to all persons with diagnosed HIV. Molecular surveillance is not new to public health – it has been used for years to track foodborne infections and diseases such as tuberculosis. Molecular HIV surveillance has become part of routine HIV surveillance and can identify transmission clusters that would otherwise go unrecognized. Molecular analysis examines the genetics of the virus, not the person. Detecting recent and ongoing HIV transmission clusters is critical to focus HIV prevention efforts where they are needed. Use of

			molecular HIV surveillance data has the potential to significantly improve HIV prevention efforts, improve health outcomes and reduce death rates for persons living with HIV, including those maintaining viral suppression. The use of molecular interventional surveillance also helps to detect drug resistance and guides the medical provider to prescribe antiretroviral therapy that is appropriate for each individual. More information is available at: https://www.cdc.gov/hiv/programresources/guidance/molecular-cluster-identification/qa.html A reference that describes the value of these specific data is available at: https://jamanetwork.com/journals/jama/fullarticle/2678246
R. Chris Wolf Vice President Chief Operating Officer SEARHC Executive Office D: 907.364.4545 M: 928.978.2167 3100 Channel Dr Ste #300 Juneau AK 99801 chrisw@searhc.org	Submitted cover letter from SouthEast Regional Health Consortium (SEARHC-Sitka) offering support for the letter from ANMC Lab Director, Dr. Tiesinga (which was attached)	As above	As above
Christopher Dela Cruz Laboratory Manager Bristol Bay Area Health Corporation 6000 Kanakanak Rd.	Submitted cover letter from Bristol Bay Area Health Corporation offering support for the letter from ANMC Lab Director, Dr. Tiesinga (which was attached)	As above	As above

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Catherine Keene Director of Health Systems Kenaitze Indian Tribe Dena'ina Wellness Center 508 Upland Street Kenai, AK 99611 (907) 335-7566 (907) 252-8753 (cell) ckeene@kenaitze.org	Submitted cover letter from Kenaitze Indian Tribe offering support for the letter from ANMC Lab Director, Dr. Tiesinga (which was attached)	As above	As above
7 AAC 27.0012			
BJ Coopes, MD, FAAP, FCCM, FWMS Providence Health & Services, Alaska Medical Director, Pediatric Intensive Care & Inpatient Pediatrics barbara.coopes@providence.org	I hope that data collected for this would include not JUST health care peeps that report (We are VERY poor at doing that), but would also gather data from any entity that collects or maintains information on birth defects, e. g., Heath insurances and any third-party administrators thereof (CMS, etc), Hospital records, Primary Care practitioner / health clinic visits / medical records, ICD-10 codes, School and other education facilities (for IEP or Special Education considerations for things such as FASD, etc.), School / Camp nursing records (eg: Respiratory "Puffin" camp, Duchene's camp, etc), Other health information exchanges / computerized medical/educational records.	Included entities that collect or maintain health care records, diagnosis, discharge, and/or claims data pertaining to a birth defect	With the increase utilization of 3rd party administrators, data aggregators, and exchanges the inclusion of these sources can be critical to more adequately identifying and capturing all children born with a birth defect in Alaska. Additionally, it can streamline identification which may ultimately lead to a reduction in burden placed upon individual health care agencies need to develop individual reports if ABDR is able to capture these diagnoses in existing data systems.
7 AAC 27.014			
N/A	No comments received	N/A	N/A

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