February 6, 2014

SUBMITTED VIA REGULATIONS.GOV

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier/OMB Control Number 0938–0581
Room C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Extension of Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations.

I. Introduction.

On December 13, 2013, the Centers for Medicare and Medicaid Services (CMS) published an Information Collection (the Notice) in the Federal Register concerning compliance with the Congressionally-mandated program with respect to the regulation of laboratory testing (CLIA).[1] In the Notice, CMS proposes to revise the CLIA Application for Certification form, CMS-116 (the Application), which must be completed and submitted by entities performing laboratory testing on specimens for diagnostic or treatment purposes.

Thank you for the opportunity to comment on the Notice. We submit these comments on behalf of the Alaska Native Tribal Health Consortium (ANTHC), a tax-exempt 501(c)(3) organization and self-governance compactor. ANTHC co-manages the Alaska Native Medical Center (ANMC), including its tertiary care hospital in Anchorage, Alaska that serves Alaska Natives and American Indians (AN/AIs) throughout the state, and is the state's only level II trauma center. ANTHC also provides a wide range of statewide public health, community health, environmental health and other programs and services for AN/AIs and their communities.

ANTHC supports the current CLIA standards, which safeguard specimen identification and integrity and promote proper communication between providers and CMS, all of which are essential for good laboratory practice. However, the Application appears to be drafted primarily

[1] Extension of Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations, 78 Fed. Reg. 75,925, 75,925 (Dec. 13, 2013).

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for facilities that have their business offices and laboratories on the same campus. By comparison, Indian Health Service (IHS) facilities and tribal health programs in Alaska and nationwide often adapt to their unique financial, demographic, and geographic challenges by managing "spokes" of small facilities from a larger central "hub." We therefore suggest a number of edits to the Application in order to address these and other concerns.

II. Discussion.

1. Section I – General Information.

Our primary concern with the General Information section is that it fails to account for facilities, like ANMC and other Tribal health programs in Alaska, that serve as administrative hubs for smaller and more remote laboratories. CMS could help remedy these issues by:

- Including a space to list a "corporate" or "contact" address. The Application currently asks for the address (both physical and mailing) for the *facility itself* being certified. But many clinical laboratories in Alaska seeking CLIA licenses are quite small, staffed solely by practitioners such as Community Health Aids, and receive their primary oversight and support from larger "parent" facilities such as ANMC. The village lab might accordingly prefer that correspondence from CMS run through ANMC and should be able to indicate as much on the Application.

- Including a space to list the name and contact information of the individual who physically completed the Application. The Application currently asks for the name of the laboratory director and the contact information for the facility itself, but not information about the person actually filling out the required forms. Numerous Tribal health programs in Alaska have reported problems in situations where CMS seeks clarifications about a particular Application by simply calling the general facility phone number listed on the Application. The CMS employee is often redirected through several layers of personnel before actually finding the staff member who filled out the Application, or ends up being directed to lab employees (rather than administrative personnel) who might not have any familiarity with the Application process. It is important that CMS be able to quickly and easily locate the correct individual with questions about an Application to ensure that it is both accurate and submitted in a timely fashion.

- Including a space for the lab to indicate where the fee coupon and CLIA certificate should be sent, if not to the lab itself. The CMS-116 currently states that the "Fee Coupon/Certificate will be mailed to the [facility] Address unless mailing address is specified." For the reasons set out above, some labs might prefer to have one or both sent elsewhere and should have the option of so indicating on the Application.

2. Section V – Multiple Sites.

Section V of the Application governs the multiple-sites exception, which allows a lab to file a single application for multiple physical facility sites in certain defined instances. We have several suggested edits to this Section.

First, one of the listed exceptions on the Application is for "a laboratory that has temporary testing sites." This is derived from CLIA regulations that authorize single applications for "[l]aboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address."[2] CMS further clarified in a December 2, 2011 memorandum to State Survey Agency Directors that for the purposes of this exception:

- A mobile laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment and records. In order to be considered a mobile unit, equipment must be installed and located permanently within the mobile unit.

- If a vehicle is used to transport laboratory equipment from the primary site/home base to another site where testing is performed, the transporting vehicle is not a mobile unit; and

- The regulation has no restrictions on the number of visits to a particular site or the type of testing performed.[3]

Absent this type of clarification, Tribal lab administrators have found it difficult to determine whether their labs qualify under this exception based solely on the very limited, non-contextualized language from the Application itself. We suggest including definitions of the terms "temporary testing sites" and "mobile units" in the Application Instructions that are referenced in Section V. For consistency's sake, these definitions should preferably incorporate the language from the regulation itself and the December 2011 memorandum.

Second, for each test conducted, Section V requires applicants to list the "specialty/subspecialty areas performed at each site." We suggest eliminating the "specialty/subspecialty" language and only requiring applicants to list "tests performed." Many administrative staff will not know what specialty/subspecialty under which a particular test must be classified, particularly for those tests that fall within multiple specialties or subspecialties. It

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[2] This clause is codified in various provisions of the CLIA regulations governing certification and registration at 42 C.F.R. §§ 493.35(b)(1), .43(b)(1), and .55(b)(1).

[3] Centers for Medicare and Medicaid Services, Office of Clinical Standards and Quality/Survey & Certification Group, *Certificate and Regulatory Multiple Site Exceptions under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)* (Dec. 2, 2011).

would be administratively more feasible for CMS agents to make this determination during the data input process than to require lab office staff to do so up front.

3. Section VIII – Non-Waived Testing.

Section VII of CMS-116 is entitled "PPM Testing" and requires disclosure of provider performed microscopy (PPM) procedures and a lab's total annual test volume for all PPM procedures. Section VIII is then entitled "Non-Waived Testing (including PPM test)" and requires disclosure of the "estimated annual test volume for each specialty" that is both non-waived and covered by CLIA.

But Section VIII does not include any specific area in which to include the total volume of PPM testing, nor does it mention PPM testing other than in the Section title. It is therefore unclear as to whether the applicant itself must add the PPM volume total from Section VII to the "Total Estimated Annual Test Volume" in Section VIII, or whether CMS will do it on the applicant's behalf. As drafted, applicants might assume that they need not include the PPM volume total from Section VII within the overall non-waived volume total in Section VIII, thus leading to errors that will unnecessarily delay the certification process.

We suggest that CMS eliminate the "(including PPM testing)" clause from Section VIII and simply instruct its staff to internally include the PPM volume total from Section VII within the overall total of Section VIII as they conduct form intake and data entry. In the alternative, CMS could remove the "(including PPM testing)" clause from Section VIII as well as the clause from Section VII requesting the total annual PPM volume, and instead include PPM as an entry in the chart in Section VIII where applicants submit the test volume of the remainder of the non-waived tests. This will help avoid duplications or omissions and improve the accuracy of submitted applications.

III. Conclusion.

Thank you for this opportunity to comments on the CLIA Application for Certification form. We look forward to your consideration of our comments and adoption of the recommendations. Do not hesitate to contact us with any questions concerning our comments.

Sincerely,

Valerie Davidson
Senior Director, Legal and Intergovernmental Affairs