

## CMS Response to Public Comments Received for CMS-116

The Centers for Medicare and Medicaid Services (CMS) received one letter containing numerous comments from the Alaska Native Tribal Health Consortium (ANTHC) relating to the Clinical Laboratory Improvement Amendments (CLIA) Application form (CMS-116). Many of the suggestions submitted by the Alaska Native Tribal Health Consortium (ANTHC) were based on the current CMS-116 form (10/10) and most of the suggestions have already been incorporated into the 2014 version of the form. Below is the reconciliation of the comments.

### **Comment:**

The Centers for Medicare and Medicaid Services (CMS) received a comment from the letter sent by the ANTHC, a tax-exempt organization that co-manages the Alaska Native medical Center (ANMC), suggesting that the CLIA Application form (CMS-116) *“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.”*

### **Response:**

**CMS is pleased to report that the revised CMS-116 will address the concern regarding the space to add a Corporate Address. The revised CMS-116 form now contains a new block to collect the Corporate Address in addition to the Physical Address and the Mailing Address.**

### **Comment:**

The Centers for Medicare and Medicaid Services (CMS) received another comment from the Alaska Native Tribal Health Consortium (ANTHC) suggesting that the CLIA Application form (CMS-116) should include *“a space to list the name and contact information of the individual who physically completed the Application.”*

### **Response:**

**CMS appreciates the suggestion but needs to point out that the CMS-116 must be signed by the individual who is responsible for the operation of the laboratory, either the laboratory owner or the laboratory director. By signing the CMS-116, the owner/director must read the consent information and understand the penalties for violating any requirement of section 353 of the Public Health Service Act.**

**CMS would also like to point out that the CMS-116 form does collect the laboratory’s email address, phone number and fax number for use in contacting the**

**laboratory for additional information or clarification. In addition, when submitting the form (via fax or mail), the laboratory has the option to include multiple contacts on a separate paper or fax cover sheet.**

**Comment:**

The Centers for Medicare and Medicaid Services (CMS) received a comment from the Alaska Native Tribal Health Consortium (ANTCH), suggesting that the CLIA application form (CMS-116) should include 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.”

**Response:**

**CMS is pleased to report that the revised CMS-116 will address your concern regarding the option to send the CLIA certificate and CLIA fee coupon space to different addresses. The laboratory applicant will have the flexibility to designate the specific address (Physical, Mailing, Corporate) for use in mailing the CLIA fee coupon and CLIA certificate. For example, the CLIA fee coupon may be sent to the Mailing Address and the CLIA certificate sent to the Physical Address.**

**Comment:**

The Centers for Medicare and Medicaid Services (CMS) received a comment from the Alaska Native Tribal Health Consortium (ANTCH), suggesting that the CMS-116 include “*definitions of the terms "temporary testing sites" and "mobile units" in the Application Instructions that are referenced in Section V."*

**Response:**

**CMS is pleased to report that Section V from the revised CMS-116 is now expanded to include the complete regulatory language to describe this multiple testing site exception. It now reads:**

**Is this a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site, such as mobile unit providing laboratory testing, health screening fairs, or other temporary testing locations, and may be covered under the certificate of the designated primary site or home base, using its address?**

**Comment:**

The Centers for Medicare and Medicaid Services (CMS) received a comment from the Alaska Native Tribal Health Consortium (ANTCH) suggesting that the CMS-116 consider *“eliminating the “specialty/subspecialty” language and only requiring applicants to list “tests performed.”*

**Response:**

**CMS thanks the commenter for the suggestion but believes the form already allows for flexibility in reporting the information on the tests performed at each of the multiple site testing locations. The space to collect the information on the form is open-ended and allows the applicant to report the test name and/or specialty and subspecialty of testing. In addition, for reference purposes, the CMS-116 package does include a chart called “Tests Commonly Performed and Their Corresponding Laboratory Specialties/Subspecialties” that provides both the test names and their associated specialties and subspecialties.**

**Comment:**

The Centers for Medicare and Medicaid Services (CMS) received a comment from the Alaska Native Tribal Health Consortium (ANTCH) suggesting that the CMS-116 *“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.”*

**Response:**

**CMS acknowledges the issues with collecting accurate counts for the Provider-performed Microscopy tests and appreciates the suggestions provided. CMS is pleased to report that when the CMS-116 was revised, CMS did enhance the form completion instructions. The parenthetical following Section VIII is now expanded to read: (Including PPM testing if applying for a Certificate of Compliance or Accreditation). Accordingly, the PPM test counts must be reported not only in the Total Estimated Annual Test Volume in Section VIII, but also beside the appropriate Specialty/Subspecialty. We provide, as part of the CMS-116 package, two charts called “Tests Commonly Performed and their Corresponding Laboratory Specialties/Subspecialties” and “Guidelines for Counting Tests for CLIA” for use in completing the form. CMS believes that these resources, along with the enhanced instructions on the CMS-116, will reduce confusion over the counting of PPM tests.**