**Summary of Proposed Changes in the ICR for the**

**National HIV Surveillance System (NHSS) OMB # 0920-0573**

**October 28, 2020**

**Summary of Changes**

We are requesting a non-substantial change to the information collection request (ICR) for the National HIV Surveillance System (NHSS) OMB #0920-0573. Specifically, we are requesting a non-substantial change to the Standards Evaluation Report (SER) as provided in Attachment 1 and the specific changes are outlined in Table 1. The changes were made to simplify language and improve clarity. The proposed form will be used by jurisdictions in January 2021 to report their 2019 outcomes. These changes will result in fewer overall questions. However, we estimate the burden to complete the new SER will remain unchanged and take one workday (approximately eight hours) to complete. Therefore, no changes to the burden table are requested. The current burden table for this ICR (with no changes) is provided in Exhibit 12.A.

Table 1. Summary of Changes to the Standards Evaluation Report (SER)

|  |  |  |  |
| --- | --- | --- | --- |
| **OMB Form 0920-0573** | **New Proposed Form** | **Changed Proposed** | **Reason for Change Proposed** |
| Pages 1-9 | Pages 1-9 | All evaluation periods are updated to reflect the 2021 report.  | To ensure that jurisdictions are reporting on the correct evaluation periods. |
| Page 2. Part B. Laboratory | Page 2. Part B. Laboratory | Question 1 was reworded. The old version:1. **In 2019, did your surveillance program do an assessment to identify all laboratories (in state and out of state) that conducted HIV-related testing for providers and facilities in your jurisdiction using a method such as a lab survey, Centers for Medicare and Medicaid Services (CMS) search, or state laboratory licensing office search? This must include more than just counting the number of labs submitting HIV-related test results to the health department.**

[ ]  Yes * Number of laboratories? Click here to enter text.
	+ Please describe how your program obtained this number. Click here to enter text.

[ ]  No* Based on eHARS data, what is the number of HIV-testing laboratoriesthat reported at least one HIV test result to your program during 2019?

|  |  |
| --- | --- |
| * Number of laboratories: Click here to enter text.
 |  |

The new version:1. **In 2020, did your surveillance program develop and/or update the list of all laboratories (in state and out of state) that conducted HIV-related testing for persons who reside in your jurisdiction using a method such as Centers for Medicare and Medicaid Services (CMS) search, or evaluation of your electronic laboratory report (ELR) program baseline spreadsheet?**

[ ]  Yes * Did you identify new laboratories that conduct HIV testing for persons who reside in your jurisdiction?

[ ]  Yes [ ]  No * What is the total number of laboratories that report HIV-related test results for persons who reside in your jurisdiction? Click here to enter text.
	+ Please describe how your program obtained this number. Click here to enter text.

[ ]  No  | Updated to clarify the meaning of and process for determining the number of laboratories reporting in a jurisdiction |
| Page 2. Part B. Laboratory | Page 2. Part B. Laboratory | Inserted the following question:1. **In 2020, did your surveillance program conduct an assessment on laboratories that conducted HIV-related testing for persons who reside in your jurisdiction? This assessment is to maintain documentation on the types of tests performed and LOINC usage by all laboratories that report to your jurisdiction.**

[ ]  Yes [ ]  No  | Updated to clarify the meaning of a laboratory assessment |
| Page 2. Part B. Laboratory | Page 2. Part B. Laboratory | Changed question 3 (formerly 2)Old version**2. Are you aware of any laboratories that conducted HIV-related testing for providers and facilities within your jurisdiction that did not report any results to your program in 2019?** [ ]  Yes * Approximately what percentage of your jurisdiction’s lab volume is missing because of this? Click here to enter text.

[ ]  NoNew version1. **Are you aware of any laboratory reporting lapses of HIV-related test results for persons who reside within your jurisdiction that resulted in missing lab data in your December 2020 data transfer? Please include lapses attributed to either the lab not reporting test results or because the HL7 reader/transmitter in the health department did not send the results to HIV surveillance**

[ ]  Yes * Approximately what percentage of your total jurisdiction’s lab volume is missing because of this? Click here to enter text.
* Approximately what percentage of all CD4 results (<200 and ≥200), or all viral load results (detectable and undetectable) are missing because of this? Click here to enter text.

[ ]  No * In 2020, did your program monitor the quality of incoming reports of laboratory test results (including test result volumes) on a quarterly basis or more frequently? [ ]  Yes [ ]  No
 | Combined and clarified questions 2 and 3 to determine if all lab test results were transmitted to CDC. |
| Page 2. Part B. Laboratory | Page 2. Part B. Laboratory | Delete original question 3 – 1. **Of the laboratory data reported to your program during 2019, are you aware of any issues that prevented your program from receiving all positive/reactive HIV detection test results, all CD4 results (<200 and ≥200), or all viral load results (detectable and undetectable) and resulted in missing lab data in your December 2019 data transfer? For example:**
	1. **Laboratory XYZ usually sends 500 viral load results each month, however, during August, undetectable viral load results were not received from Laboratory XYZ and the problem was not resolved by December 2019; or**
	2. **Laboratory XYZ was transmitting all viral load result but the HL7 ELR reader/transmitter in the health department did not send the test results to the HIV program**

[ ]  No* In 2019, did your program monitor the quality of incoming reports of laboratory test results (including test result volumes) on a quarterly basis or more frequently? [ ]  Yes [ ]  No

[ ] Yes

|  |  |
| --- | --- |
| * Approximately what percentage of all test results in a given year is typically reported by this laboratory or laboratories?
 | Click here to enter text. |
| * Approximately what percentage of the test results expected from this laboratory or laboratories in 2019 was not received?
 | Click here to enter text. |
| * Please describe the expected test results that were not received from this laboratory or laboratories: Click here to enter text.
 |

 | Combined and clarified questions 2 and 3 to determine if all lab test results were transmitted to CDC |
| Page 3. Part B. Laboratory | Page 3. Part B. Laboratory | Edit paragraph 4:Deleted columns titled “If “no”, what % of results received have been transferred to CDC?”Also edited two headings:* “CD4 Results” became “CD4 (< 200 and ≥ 200)”
* “Viral load results” became “Viral load tests (detectable and undetectable)”
 | Shortened and clarified this to determine what CD4 and VL are being transmitted to CDC |
| Page 3. Part C. Pediatric/Perinatal  | Page 3. Part C. Pediatric/Perinatal | For the first question on “Birth Ascertainment,” deleted “and infants with HIV infection not [reported to surveillance, and enter the results into eHARS” | Revised so that the question is specific to completing linkage activities. A new question (1C) was added to assess the status of entering the results of the linkage into eHARS. This change allows HICSB to be able to differentiate between jurisdictions who completed the linkage but did not enter the results into eHARS and jurisdictions who did not complete the linkage. |
| Page 3. Part C. Pediatric/Perinatal | Page 3. Part C. Pediatric/Perinatal | Inserted three follow-up questions to 1A. One is a yes/no question but two require text responses. The three questions include:“1B. If no to 1A, please describe why you did not link with all state/local birth certificate data.[Free text]”“1C. If yes to 1A, did you enter all information identified from the linkage to state/local birth certificate data into eHARS before your final December 2020 data transfer to CDC?[ ]  Yes [ ]  No ““ID. If no to 1C, please describe why you did not enter all information identified from the link to state/local birth certificate data into eHARS.[Free text]” | For 1B – To understand why jurisdictions did not link to all state/local birth certificate data so that HICSB can better tailor technical assistance to support conducting this required activity.For 1C – To assess the status of entering the results of the linkage into eHARS. This change allows HICSB to be able to differentiate between jurisdictions who completed the linkage but did not enter the results into eHARS and jurisdictions who did not complete the linkage.For 1D – To understand why jurisdictions completed the linkage but did not enter the results into eHARS so that HICSB can better tailor technical assistance to support conducting this required activity. |
| Page 3. Part C. Pediatric/Perinatal | Page 3. Part C. Pediatric/Perinatal | Moved the following question to the “Outcomes Standards for Surveillance”“Did ≥ 85% of perinatally exposed infants born in 2018 have HIV infection status determined by 18 months of age?” | This measure is actually an outcome measure for perinatally exposed infants and so it should be in the “Outcome Standards for Surveillance” section. |
| Page 3. Part C. Pediatric/Perinatal | Page 3. Part C. Pediatric/Perinatal | With regard to Number of perinatally HIV exposed infants for birth year, inserted the following two questions:Does this match with the number of perinatally exposed infants reported to CDC through your final December 2020 data transfer? ☐ Yes ☐ No And:“If this does not match, please describe the reasons the numbers do not match (e.g., X perinatally exposed infants reported to health department that were not in the state/local birth certificate data because the infant was a resident of another jurisdiction).” | Data quality reviews identified discrepancies in the number of perinatally HIV exposed infants reported through the surveillance system versus on the Standards Evaluation Report. This information will help HICSB assess and target assistance to improve the accuracy of the number of perinatally HIV exposed infants. Accurate information is necessary in order to monitor progress eliminating perinatal HIV transmission. |
| Page 4. Part E. Cluster Detection and Response | Page 4. Part E. Cluster Detection and Response | The following sentence was edited to: In ~~2019~~ 2020, did your program develop and submit a written plan for establishing and maintaining capacity for cluster and outbreak detection and response according to CDC guidance? | Updated the year of interest and added ‘written draft’ to reflect the requirement that jurisdictions were expected to submit a written draft cluster and outbreak response plan. |
| Page 7.Part G. Submission of Required Outcome Standards without SAS Tables | Page 7.Part G. Submission of Required Outcome Standards without SAS Tables | The following note was added to this section:**Note: This section is optional since cluster detection activities were not required for all of 2019.**  | Add this note to clarify that filling out this section is optional.  |
| Page 7.Part G. Submission of Required Outcome Standards without SAS Tables | Page 7.Part G. Submission of Required Outcome Standards without SAS Tables | The following edit was made to the footnote:For the two Testing/re-testing and PrEP Referral standards above, please briefly discuss what you plan to do in in the coming year ~~how you plan~~ to improve testing/re-testing and PrEP referral outcomes for persons in clusters and risk networks. ~~In 2021.~~  | Made minor edits to clarify fhernootnote on table. |

Exhibit 12.A Estimate of Annualized Burden Hours.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Form Name | No. of Respondents | No. of Responses per Respondent | Total No. of Annual Responses | Avg. Burden per Response (in hours) | Total Annual Burden (in hours) |
|
| Adult HIV Case Report(att 3a,3c,4a)  | 59 | 854 | 50,386 | 20/60 | 16,795 |
| Pediatric HIV Case Report (att 3b,3c,4b) | 59 | 3 | 177 | 20/60 | 59 |
| Case Report Evaluations (att 3a,3b,3c) | 59 | 86 | 5,074 | 20/60 | 1,691 |
| Case Report Updates (att 3a,3b,3c,4a,4b) | 59 | 2353 | 138,827 | 2/60 | 4,628 |
| Laboratory Updates (att 3a,3b,3c,4a,4b) | 59 | 9410 | 555,190 | 0.5/60 | 4,627 |
| Deduplication Activities (att 4c) | 59 | 2741 | 161,719 | 10/60 | 26,953 |
| Investigation Reporting and Evaluation (att 3c,4d,4e) | 59 | 901 | 53,159 | 1/60 | 886 |
| Initial Cluster Report Form (att 3f,4f) | 59 | 2.5 | 148 | 1 | 148 |
| Cluster Follow-up Form (att 3g,4f) | 59 | 5 | 295 | 30/60 | 148 |
| Cluster Close-out Form (att 3h, 4e) | 59 | 2.5 | 148 | 1 | 148 |
| Perinatal HIV Exposure Reporting (PHER) (att 3c,3d,4b)  | 16 | 197 | 3,152 | 30/60 | 1,576 |
| HIV Incidence Surveillance (HIS) (att. 3a, 3c, 4a) | 7 | 2,282 | 15,974 | 5/60 | 1,331 |
| Annual Reporting:Standards Evaluation Report (SER)(att 3e)  | 59 | 1 | 59 | 8 | 472 |
| Total Burden |  |  |  |  | 59,462 |

Note: The estimates of total annualized burden hours are based on the estimated total number of case reports (i.e., Total No. Annual Responses) expected to be completed by state and local health departments each year (see narrative for description)

Attachment 1.2019 Standards Evaluation Report (SER)