

Non-material/non-substantive change request
Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments
Approved OMB No. 0920-1353 Exp. Date 11/30/2024

NARRATIVE Description of Changes:

Changes requested to the Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments Information Collection Request package (OMB No. 0920-1353) are intended to improve clarity, readability, flow, and efficiency for recipients. None of the changes requested will increase their reporting burden so there is no change to the burden table. For example, after incorporating the requested changes, two forms will be consolidated into one for simplicity (i.e., the information on Att 3f will be addressed with similar content on Att 3a, and Att 3f will be eliminated). In addition, several questions on two data collection forms (Att 3a, Att 3b) have been reworded for clarity, but the requested information has not changed. Likewise, explanatory information on three supporting documents (line-item instructions Att 4a, Att 4b, Att 4c) has been modified for clarity and simplicity, but will not impact burden of completion.

| Form | Current Question/Item/Page | Requested Change | Rationale |
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| Att 3a_Component 1_5-28-2021 | Page 5, Measure 1.2.1.a Are HBV DNA results reportable in your jurisdiction? Does your health department receive reports of negative HBV DNA results? | Delete current questions and replace with questions from approved form Att 3f_Acute Viral Hepatitis Case Reporting_6-9-2021: Are negative hepatitis B surface antigen (sAg) results currently reportable in your jurisdiction? Are negative hepatitis B sAg results currently received by your health department? If “Yes, all...” what was the first <u>full</u> reporting year that <u>all</u> negative hepatitis B sAg results were available in your jurisdiction? Are negative HBV DNA results currently reportable in your jurisdiction? Are negative HBV DNA results currently received by your health department? If “Yes, all...” what was the first <u>full</u> reporting year that <u>all</u> negative HBV DNA results were available in your jurisdiction? | Consolidates two forms into one for simplicity, clarity, improved flow, easier readability, increased efficiency (will allow us to remove Att 3f_Acute Viral Hepatitis Case Reporting_6-9-2021 from package) |
| Att 3a_Component 1_5-28-2021 | Page 5, Measure 1.2.1.a Are HCV RNA results reportable in your jurisdiction? Does your health department receive reports of negative HCV RNA results? | Delete current questions and replace with questions from approved form Att 3f_Acute Viral Hepatitis Case Reporting_6-9-2021: Are negative hepatitis C antibody (anti-HCV) results currently reportable in your jurisdiction? Are negative anti-HCV results currently received by your health department? If “Yes, all...” what was the first <u>full</u> reporting year that <u>all</u> negative anti-HCV results were available in your jurisdiction? Are negative / undetectable HCV RNA results currently reportable in your jurisdiction? Are negative / undetectable HCV RNA results currently received by your health department? If “Yes, all...” what was the first <u>full</u> reporting year that <u>all</u> negative HCV RNA results were available in your jurisdiction? | Consolidates two forms into one for simplicity, clarity, improved flow, easier readability, increased efficiency (will allow us to remove Att 3f_Acute Viral Hepatitis Case Reporting_6-9-2021 from package) |
| Att 3a_Component 1_5-28-2021 | Page 9, Measure 1.2.4.a | Modify questions to read: | Reworded for clarity and |

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| | <p>Are you reporting hepatitis C viral clearance cascade data? Have you prepared and disseminated an annual viral hepatitis surveillance report that includes hepatitis C surveillance data?</p> | <p>Have you developed a hepatitis C viral clearance cascade? If hepatitis C viral clearance cascade “Completed,” please indicate when the most recent cascade was completed and provide the URL for—or a copy of—the cascade.</p> | simplicity |
| Att 3a_Component 1_5-28-2021 | <p>Page 9, Measure 1.2.5.a Does your annual viral hepatitis surveillance report include hepatitis C viral clearance cascade data? Please provide URL for report, if available Date report was posted, if applicable (MM/DD/YYYY)</p> | <p>Modify questions to read: Have you developed a viral hepatitis surveillance report? If viral hepatitis surveillance report “Completed,” please indicate when the most recent report was completed and provide the URL for—or a copy of—the report.</p> | Reworded for clarity and simplicity |
| Att 3a_Component 1_5-28-2021 | Page 10 | <p>Add questions from approved form Att 3f_Acute Viral Hepatitis Case Reporting_6-9-2021: Among all the newly reported hepatitis B cases (acute and chronic) in 2019 among individuals ≤40 years of age, what proportion had an unknown anti-HBc IgM result? Among those cases that had an unknown anti-HBc IgM result, what proportion were investigated? Among all newly reported hepatitis C cases (acute and chronic) in 2019 among individuals ≤40 years of age, what proportion of cases were investigated by a public health department? Of all of the hepatitis A, acute hepatitis B, and acute hepatitis C infections that you believe (or have estimated) occurred in your jurisdiction in 2019, what proportion do you believe were: 1) reported to the state or local health department in your jurisdiction and 2) a notification was sent to CDC?</p> | Consolidates two forms into one for simplicity, clarity, improved flow, easier readability, increased efficiency (will allow us to remove Att 3f_Acute Viral Hepatitis Case Reporting_6-9-2021 from package) |
| Att 3f_Acute Viral Hepatitis Case Reporting_6-9-2021 | Entire form | Delete (Content has been moved to Att 3a_Component 1_5-28-2021) | Consolidates two forms into one for simplicity, clarity, improved flow, easier readability, increased efficiency |
| Att 3b_Component 2_5-28-2021 | <p>Page 2, Measure 2.1.1.a Does the committee (or coalition) plan to support elimination for hepatitis C and/or hepatitis B? If the committee (or coalition) met during this reporting period, please submit a copy of meeting agenda(s).</p> | <p>Add word “planning”: Does the committee (or coalition) plan to support elimination planning for hepatitis C and/or hepatitis B? Add “with the APR”: If the committee (or coalition) met during this reporting period, please submit a copy of meeting agenda(s) with the APR.</p> | Reworded for clarity |

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| Att 3b_Component 2_5-28-2021 | Page 2, Measure 2.1.1.c If the viral hepatitis elimination plan is completed, please submit a copy. | Add “with the APR”: If the viral hepatitis elimination plan is completed, please submit a copy with the APR. | Reworded for clarity |
| Att 4a_Comp 1 instructions_5-18-2021 | Page 1 | Add explanatory summary at beginning: Note: Timelines are provided for each measure, however in general: <ul style="list-style-type: none"> • Short-term outcomes should be reached by the end of year 3. Measures associated with these outcomes should be reported each year. Recipient can define year 1 goal, and year 2 goal should be determined based on interim activities. • Intermediate outcomes should be reached by the end of year 5. Measures associated with these outcomes should be reported each year. • Outcomes for measures that are “contingent on funding” are not required to be reached unless funded during the course of the award. Reporting of these measures is recommended but not required. Remove individual instructions on page 2 (now covered by explanatory summary at beginning) | Added for clarity |
| Att 4a_Comp 1 instructions_5-18-2021 | Page 8, Measure 1.2.4.a <ul style="list-style-type: none"> • This is an intermediate outcome (years 3–5). • Beginning in year 3, use jurisdiction-specific data, including undetectable HCV RNA, mortality data, and other data as available to monitor the hepatitis C viral clearance cascade. • Additional guidance on preparing and reporting hepatitis C viral clearance cascade data will be shared by CDC. | Update language to reflect changes to Att 3a_Component 1_5-28-2021, page 9 (above): <ul style="list-style-type: none"> • This is an intermediate outcome (years 4–5). • Use jurisdiction-specific data, including undetectable HCV RNA, mortality data, and other data as available to monitor the hepatitis C viral clearance cascade. • Date cascade was completed (MM/DD/YYYY) — Enter the date the hepatitis C viral clearance cascade was completed. • URL — Please provide the URL for the most hepatitis C viral clearance cascade, if available. If no URL is available, please submit a copy of the cascade with the APR. • Additional guidance on preparing and reporting hepatitis C viral clearance cascade data will be shared by CDC. | Reworded for clarity |
| Att 4a_Comp 1 instructions_5-18-2021 | Page 8, Measure 1.2.5.a <ul style="list-style-type: none"> • This is an intermediate outcome (years 3–5). • Beginning in year 3, produce and disseminate an annual surveillance report that includes hepatitis A, acute hepatitis B, and acute and chronic hepatitis C | Update language to reflect changes to Att 3a_Component 1_5-28-2021, page 9 (above): <ul style="list-style-type: none"> • This is an intermediate outcome (years 4–5). • Produce and disseminate an annual surveillance report that includes hepatitis A, acute hepatitis B, and acute and chronic hepatitis C surveillance data, as well as hepatitis C viral clearance cascade data. • Date report was completed (MM/DD/YYYY) — Enter the date the most recent surveillance report was completed. | Reworded for clarity |

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| | <p>surveillance data, as well as hepatitis C viral clearance cascade data.</p> <ul style="list-style-type: none"> • URL — Please provide the URL for the most recent surveillance report, if available. • Date report was posted (MM/DD/YYYY) — Enter the date the most recent surveillance report was posted. | <ul style="list-style-type: none"> • URL — Please provide the URL for the most recent surveillance report, if available. If no URL is available, please submit a copy of the report with the APR. | |
| Att 4a_Comp 1 instructions_5-18-2021 | Page 8 | <p>Add instructions for questions added to Att 3a_Component 1_5-28-2021, page 10 (above): To be completed in YEAR 1 ONLY</p> <ul style="list-style-type: none"> • These are short-term outcomes to be completed in Year 1 only. • Please select the appropriate percentage. • For the last question, please provide a brief justification for the answer you selected for each acute viral hepatitis infection. | |
| Att 4a_Comp 1 instructions_5-18-2021 | Pages 8, 11, 12 This is an intermediate outcome (years 3-5). | Year 3 should read Year 4. Change to: This is an intermediate outcome (years 4-5). | Modified for accuracy |
| Att 4b_Comp 2 instructions_5-28-2021 | Page 1 | <p>Add explanatory summary at beginning: Note: Timelines are provided for each measure, however in general:</p> <ul style="list-style-type: none"> • Short-term outcomes should be reached by the end of year 3. Measures associated with these outcomes should be reported each year. Recipient can define year 1 goal, and year 2 goal should be determined based on interim activities. • Intermediate outcomes should be reached by the end of year 5. Measures associated with these outcomes should be reported each year. • Outcomes for measures that are “contingent on funding” are not required to be reached unless funded during the course of the award. Reporting of these measures is recommended but not required. <p>Remove individual instructions on pages 5-9 (now covered by explanatory summary at beginning)</p> | Added for clarity |
| Att 4b_Comp 2 instructions_5-28-2021 | Page 3, Measure 2.1.2.a Laboratory identification — In year 1, | Add sentence (in bold): Laboratory identification — In year 1, each jurisdiction should work | Added for clarity |

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| | each jurisdiction should work with their surveillance and/or epidemiology teams to identify the total number of CLIA-certified laboratories in their jurisdiction that report hepatitis C antibody testing results. | with their surveillance and/or epidemiology teams to identify the total number of CLIA-certified laboratories in their jurisdiction that report hepatitis C antibody testing results. Labs included could be CLIA-certified labs conducting hepatitis tests or labs conducting hepatitis tests under CLIA. | |
| Att 4b_Comp 2 instructions_5-28-2021 | Page 3, Measure 2.1.2.b Needs assessment — By the end of year 1, each jurisdiction should, in consultation with the technical advisory committee (or coalition), conduct a needs assessment that describes the current hepatitis C antibody and HCV RNA reflex testing practices among this subset of laboratories and identifies key barriers and challenges to HCV RNA reflex testing. | Add sentence (in bold): Needs assessment — By the end of year 1, each jurisdiction should, in consultation with the technical advisory committee (or coalition), conduct a needs assessment that describes the current hepatitis C antibody and HCV RNA reflex testing practices among this subset of laboratories and identifies key barriers and challenges to HCV RNA reflex testing. Laboratories that routinely perform RNA reflex testing on all HCV antibody positive test (e.g., QUEST Diagnostics, etc.) should be included in the numerator, but jurisdictions do not need to conduct a detailed needs assessment. | Added for clarity |
| Att 4c_Comp 3 instructions_5-18-2021 | Page 1 | Add explanatory summary at beginning: Note: Timelines are provided for each measure, however in general: <ul style="list-style-type: none"> • Short-term outcomes should be reached by the end of year 3. Measures associated with these outcomes should be reported each year. Recipient can define year 1 goal, and year 2 goal should be determined based on interim activities. • Intermediate outcomes should be reached by the end of year 5. Measures associated with these outcomes should be reported each year. • Outcomes for measures that are “contingent on funding” are not required to be reached unless funded during the course of the award. Reporting of these measures is recommended but not required. Remove individual instructions on pages 1–10 (now covered by explanatory summary at beginning) | Added for clarity |