**Request for Nonmaterial/Non-substantive change**

**Validated Follow-up Interview of Clinicians on Outpatient Antibiotic Stewardship Interventions (42 CFR 247d-5)**

**(OMB Control No. 0920-1308)**

**Expires 03/31/2022**

**Program Contact**

Thomas Daymude

Division of Healthcare Quality Promotion (DHQP)

Centers for Disease Control and Prevention

1600 Clifton Road, NE

Atlanta, Georgia 30333

Phone: (687) 313-4643

Email: qkh7@cdc.gov

**Submission Date:** 10/20/2021

**Circumstances of Change Request for OMB 0920-1308**

The Centers for Disease Control and Prevention (CDC), Division of Healthcare Quality Promotion (DHQP) requests a nonmaterial/non-substantive change of the currently approved Information Collection Request: Validated Follow-up Interview of Clinicians on Outpatient Antibiotic Stewardship Interventions (42 CFR 247d-5).

The changes to the previous submission are for greater clarity and reduction of burden. Clarifying language has been added to reduce confusion that was identified after soliciting input from representatives of the target respondent population during initial testing of the survey. The structure of survey questions was also changed to reduce burden on respondents. Rather than providing twelve responses for each of eight interventions (96 responses total), respondents are now providing twelve responses for each of seven core elements and answering two summary questions (86 responses total). Now, respondents are given the option to skip an element if they report having no experience with the element. Additional recruitment strategies are proposed to improve response rate of the respondent pool. Only formatting of the consent cover letter has changed with minimal content changes to add transparency or clarity. The new submission is like the one outlined in OMB Control Number 0920-1308 Validated Follow-up Interview of Clinicians on Outpatient Antibiotic Stewardship Interventions, with certain changes to reduce respondent burden and provide additional instructional clarity, as described below.

Description of the changes

The changes to the consent cover letter are as follows:

1. The letter has been digitized and some elements have been moved or removed.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
| Version 4.0 | Version 5.0 |
| IRB number in bottom right corner | IRB number located at top left for electronic version |
| No identification of funding source | Funding source identified as CDC |
| No conflict disclosure | Disclosure identifies no conflicts |
| Refers to semi-structured interview | Semi-structured interview references removed |
| No mention of alternatives | Alternative to participation listed as not participating |
| No mention of publication of study results | Results are noted to be publicly available through future publication of academic products |
| Noted that identifiable information won’t be collected | Removed note about identifiable information since it may be used to distribute and track responses to target reminders  |
| No mention of whether there will be commercial profit from the study | Specified there is no intent to commercially profit from the data collected in the survey |
| No mention of cost to participate | Specified no financial cost to participate |
| Thank you statement as part of the consent cover letter | Thank you is now provided after the survey is completed |

The changes will make the content layout more compatible with electronic presentation and consistent with standard consent cover letter formatting.

1. The estimated time to complete the survey has been updated.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
| This semi-structured interview should take up to 20 minutes depending on your answers. | This survey should take up to 10 minutes depending on your answers. |

The update will reflect the change in estimated time to complete the survey based on preliminary testing by confederate representatives of the target respondent population on the research team and will provide more transparency of time commitment to respondents.

The changes to the survey instrument (SSA Attachment 3) are as follows:

1. There are some instructions added to the beginning of the survey.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
| No instructions | When responding to this survey:* Each group of prompts is part of one measure. Please take great care to answer each prompt independently.
* Prompts using similar terms may capture different aspects of each measure.
* Use your best judgment when interpreting the meaning of each prompt based on the terms used.
 |

The addition of these instructions will add clarity to help the respondents better understand the nature of the psychometric assessment.

1. There is a change in language describing the elements measured by the survey.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
| CDC Core Elements | Core Elements of the Urgent Care Antibiotic Stewardship Program |

The change will more accurately convey that the interventions are based on elements that are further derived from the CDC Core Elements of Outpatient Antibiotic Stewardship and more specific to institution-level implementation.

1. There is a change in how respondents were prompted 12 times (4 prompts for each of the 3 psychometric measures) for each of 8 interventions to now being prompted for representative interventions of each of 7 elements of the program. Respondents are now given the option to skip an element if they report having no experience with the element. Some interventions appear with different names that are more familiar to the respondent pool.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
|  |  |
| 12 prompts for EACH of 8 interventions:1. Delayed Prescriptions
2. Quick Visit templated notes
3. Azithromycin Justification
4. Prescribing Dashboard
5. Professional conversations to review quality measures
6. Patient symptoms checklist
7. Site visits
8. Commitment posters
 | 12 prompts for representative interventions from EACH of 7 elements:1. Clinician Education (select one or none)
	* Infectious Diseases Updates During In-Person Meetings
	* Opportunities to Consult Infectious Diseases Experts
	* Antibiotic Stewardship Website Resources
2. Access to Internal Guidelines (select one or none)
	* CPMs
	* Flash Cards
3. iCentra Tools (select one or none)
	* Azithromycin Justification Alerts
	* Quick Visits
4. Shared Decision Making (select one or none)
	* Electronic/Written Delayed Prescriptions
	* Watchful Waiting Handouts
5. Patient-Focused Marketing (select one or none)
	* Waiting Room Posters
	* Reception Area Desk & Door Wraps
6. Leadership Commitment (select one or none)
	* Leadership Commitment Posters
7. Transparent Data & Feedback (select one or none)
	* Antibiotic Prescribing Dashboards (Provider and Clinic Level Views)
	* Professional Conversations with Associate Medical Directors
 |

The change to element-targeted prompts will allow for significant reduction in respondent burden without compromising data collection. At baseline, there will be 12 fewer prompts to complete, and this will further be reduced if a respondent reports no experience with any element. The changes to the nomenclature will appeal to familiarity, improve response quality, and are informed by preliminary testing of the instrument by confederate representatives of the target respondent population on the research team.

1. Respondents are given guidance in the subheading of each psychometric measure.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
| No guidance provided for AIM | Consider how agreeable or satisfactory these were to you personally. |
| No guidance provided for IAM | Consider how these fit into or were compatible with the setting in which you see patients. |
| No guidance provided for FIM | Consider how easy or convenient these were to implement in the setting where you see patients. |

The addition of guidance will add clarity to improve quality and reduce time spent on responses. It is informed by preliminary testing of the instrument by confederate representatives of the target respondent population on the research team.

1. Language was updated for each of the psychometric measures.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
| (INSERT INTERVENTION) meets my approval | (INSERT INTERVENTION) met my approval |
| (INSERT INTERVENTION) is appealing to me | (INSERT INTERVENTION) were appealing to me |
| I like (INSERT INTERVENTION) | I liked (INSERT INTERVENTION) |
| I welcome (INSERT INTERVENTION) | I welcomed (INSERT INTERVENTION) |
| (INSERT INTERVENTION) seem fitting | (INSERT INTERVENTION) were fitting |
| (INSERT INTERVENTION) seem suitable | (INSERT INTERVENTION) were suitable |
| (INSERT INTERVENTION) seem applicable | (INSERT INTERVENTION) were applicable |
| (INSERT INTERVENTION) seem like a good match | (INSERT INTERVENTION) were a good match |
| (INSERT INTERVENTION) seem implementable | (INSERT INTERVENTION) were implementable |
| (INSERT INTERVENTION) seem possible | (INSERT INTERVENTION) were possible |
| (INSERT INTERVENTION) seem doable | (INSERT INTERVENTION) were doable |
| (INSERT INTERVENTION) seem easy to use | (INSERT INTERVENTION) were easy to use |

The updates will correct for grammatical mismatch identified during testing of the electronic branching logic and will adapt the instrument to reflect the recommendations of the confederate representatives of the target respondent population on the research team. This was done for greater ease in using the survey instrument.

1. Respondents are asked two final questions related to their perceptions of which elements were most responsible for influencing personal prescribing practices and systematic prescribing practices.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
| Question did not exist previously | What was the single most important element that influenced **YOUR** prescribing practices? |
| Question did not exist previously | What was the single most important element that influenced the **SYSTEM** to change prescribing practices? |

The addition will allow researchers to better understand respondent perspectives and improve the semi-structured interview guide that will be revised based on the data from the responses to this instrument.

The changes to the recruitment templates for data collection (SSA Attachment 5) are as follows:

1. In addition to email recruitment, the Microsoft Teams workspace platform, SMS, and printed index cards will be used to recruit respondents to the survey. References to the semi-structured interview have been removed.

The additional methods of recruitment will increase the response rate for the survey. Semi-structured interview content will be submitted in a separate approval request.

1. The survey initial recruitment email subject line has been updated.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
| Subject Line: Intermountain Provider Survey – please share your responses about Antibiotic Stewardship  | Subject Line: Intermountain Urgent Care Survey – please participate in a 10-minute survey about the Antibiotic Stewardship program |

The change to the subject line will encourage a higher response rate by providing transparency about the time commitment for completion of the survey.

1. The survey initial recruitment email content has been updated.

|  |  |
| --- | --- |
| Dear [Provider Name], You are being contacted to participate in a research project investigating provider attitudes and behaviors related to antibiotic stewardship. We need your help! In July 2019, Intermountain implemented several new antibiotic stewardship interventions within our urgent care service line as part of our contract with the CDC. As part of that work, we want to hear about *your* experiences with these interventions and what you’ve observed. Have you changed your practice? Are you providing more education to patients about antibiotic use? What tools and techniques have been useful for helping you improve your prescribing? The results of this survey will be used to understand the effects of our interventions and how they can be generalized and improved. TAKE SURVEYYour survey link is: [REDCap Link] For questions or concerns, please contact the research team by sending an email to scoreuc@imail.org or by calling (801)382-7483 between 7 a.m. - 7 p.m. Monday through Thursday or 7 a.m. - 5 p.m. Friday. Thank you for your interest in being part of our research! Sincerely, Kim Brunisholz Lead Qualitative Scientist, Healthcare Delivery Institute, Intermountain Healthcare You received this email because you were an urgent care provider during our stewardship interventions implementation period from July 2019 to June 2020. We will send two more reminders to participate unless you Unsubscribe.  | Hello!You are being invited to participate in 10-minute survey about the Urgent Care Antibiotic Stewardship program sponsored by Drs. Tony Wallin and Eddie Stenehjem.Why are we asking for help?We need to understand how stewardship interventions have improved antibiotic prescribing in Urgent Care.Why is your help important?We need to understand what stewardship interventions work best for patients and clinicians. By giving your feedback, it will help us identify only the interventions that are most necessary to improve prescribing.We have made it as easy as possible to give your feedback.Click on the link or scan the QR code below to participate. This link is unique to you and should not be forwarded to others.(QR CODE)[survey-link]If the link above does not work, try copying the link below into your web browser: [survey-url] |

The changes to the content of the initial recruitment email will reduce word count and provide essential information about the survey. We have also included a QR code as an option allowing participants to respond using mobile devices, which may add convenience and increase response rate.

1. The survey follow-up recruitment email content has been updated.

|  |  |
| --- | --- |
| Dear [Provider Name], We recently sent you an invitation to participate in a survey about antibiotic stewardship. The results will be used to provide important information to health systems across the country. We want to hear from you! Please respond no later than July 23, 2021.TAKE SURVEYYour survey link is: [REDCap Link] For questions or concerns, please contact the research team by sending an email to scoreuc@imail.org or by calling (801)382-7483 between 7 a.m. - 7 p.m. Monday through Thursday or 7 a.m. - 5 p.m. Friday. Thank you for your interest in being part of our research! Sincerely, Tony Wallin Medical Director, Urgent Care Service Line, Intermountain Healthcare You received this email because you were an urgent care provider during our stewardship interventions implementation period from July 2019 to June 2020. We will send two more reminders to participate unless you Unsubscribe. | Hello again,This is a courtesy reminder that you are invited to participate in a 10-minute survey about the Urgent Care Antibiotic Stewardship program sponsored by Drs. Tony Wallin and Eddie Stenehjem.Why we are asking for help?We need to understand how stewardship interventions have improved antibiotic prescribing in Urgent Care.Why your help is important?We need to understand what stewardship interventions work best for patients and clinicians. By giving your feedback, it will help us identify only the interventions that are most necessary to improve prescribing.We have made it as easy as possible to give your feedback.Click on the link or scan the QR code below to participate. This link is unique to you and should not be forwarded to others.(QR Code)[survey-link]If the link above does not work, try copying the link below into your web browser: [survey-url] |

The changes to the content of the follow-up recruitment email will re-iterate essential information about the survey. We have also included a QR code as an option allowing participants to respond using mobile devices, which may add convenience and increase response rate.

1. A template for the reminder in Microsoft Teams was added to the document.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
| Did not exist previously  | Hello, you are being invited to participate in a 10-minute survey to better understand how stewardship interventions have improved antibiotic prescribing in Urgent Care.Please use the survey link below to participate.[Sample Public Survey Title Link]If the link above does not work, try copying the link below into your web browser: https://intermountainhealthcare.org/redcapsurveys/surveys/?s=SAMPLE\_LINK |

The use of Microsoft Teams in survey recruitment will increase visibility of the survey and will increase response rate.

1. A template for the SMS reminder was added to the document.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
| Did not exist previously | Hello, please help us with this antibiotic prescribing survey [Link] – Intermountain Healthcare SCORE Ambulatory Projects Team |

The use of SMS in survey recruitment will capitalize on knowledge that the intended pool of participants is most easily reached using SMS. The survey is optimized for mobile use and the convenience of providing this method of participation will increase response rate.

1. A template for the Printed Index Cards was added to the document.

|  |  |
| --- | --- |
| **Changed from…** | **Changed to…** |
| Did not exist previously | Got 10 Minutes?Help Intermountain researchers understand how stewardship interventions have improved antibiotic prescribing.(QR Code)Scan the QR code with your phone to get started! |

The use of printed index cards in survey recruitment will raise awareness of the survey opportunity while potential participants are in the clinic setting. The survey is optimized for mobile use and the convenience of providing this method of participation optional way to spend downtime will increase response rate.

Burden

The change in recruitment methods and frequency, the survey guidance verbiage, the reduced total number of survey prompts for intervention measures with the option to skip prompts for indicated elements, and the two additional multiple-choice questions allows for an overall reduction of burden for the survey implementation. While this may not materially change the burden for some respondents, the overall burden for all respondents participating in the survey is anticipated to be lower. There are no additional privacy considerations.