

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF CUSTOMER SATISFACTION SURVEYS (0910-0360)

The generic clearance will only be used for customer satisfaction and website usability surveys where FDA seeks to gather information that is planned for internal use only, and can provide a justification for qualitative or anecdotal collections that may nonetheless produce useful information for program and service improvement.

TITLE OF INFORMATION COLLECTION: Sponsor and Payor Feedback for the Early Payor Feedback Program

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

At the conclusion of the sponsors and payors' interactions through our Early Payor Feedback Program, we ask for feedback from the sponsors and the payors on their individual experiences. More information on our Early Payor Feedback program can be found at:

<https://www.fda.gov/about-fda/cdrh-innovation/payor-communication-task-force#2>.

2. **Intended use of information:**

We use the sponsor and payor feedback to refine our Early Payor Feedback Program and to demonstrate the impact of the program to internal stakeholders.

3. **Description of respondents:**

Medical device manufacturers (sponsors), and public and private organizations that pay for health care (payors) who have participated in our Early Payor Feedback Program.

4. **Date(s) to be Conducted:**

The survey for the payor respondents will begin after OMB approval. The survey for the sponsors will begin April 15, 2022.

5. **How the Information is being collected:**

Respondents are first contacted via email to set up a time to conduct the survey via phone. We are exploring the potential use of survey monkey (or similar), or fillable pdf for easier data collection. The survey monkey will be used for the sponsor survey, but not the payor survey. We'd like to still be able to talk on the phone with our payor partners. We hope to explore the use of survey monkey, or similar platform, over the next few months, and maybe use it for the April 15, 2022 sponsor feedback survey. We will provide screen shots once they are available.

6. **Confidentiality of Respondents:**

"Your participation/non-participation is completely voluntary and your responses will not have an effect on your eligibility for receipt of any FDA services. All respondent identification and information will be anonymous unless otherwise indicated. In instances where respondent identity is needed (e.g., for follow-up of non-respondents),

this information collection fully complies with all aspects of the Privacy Act and data will be kept secure to the fullest extent allowed by law.”

7. Amount and justification for any proposed incentive

No incentive is proposed.

8. Questions of a Sensitive Nature (Data will be kept private to the extent allowed by the law)

We will not be collecting data that is of a sensitive nature.

9. Description of Statistical Methods

BURDEN HOUR COMPUTATION (*Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours*):

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Sponsor	15 per year	30 minutes	8
Payor	7 per year	60 minutes	7
Total	22 per year		15

REQUESTED APPROVAL DATE: September 2021

NAME OF PRA ANALYST & PROGRAM CONTACT:

Ila. S. Mizrachi
Paperwork Reduction Act Staff
Ila.mizrachi@fda.hhs.gov
301-796-7726

Brandy Edmonds
301-796-8676
Brandy.Edmonds@fda.hhs.gov

Kelly Wilkicki
301-796-4608
Kelly.Wilkicki@fda.hhs.gov

FDA CENTER: Center for Devices and Radiological Health