

Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB Control Number: 10415)

TITLE OF INFORMATION COLLECTION: Health Care Consumer Feedback on Open Payments National Transparency Program (Open Payments)

PURPOSE:

Under the Physician Payments Sunshine Act (PPSA), drug and medical device companies must disclose to the Centers for Medicare & Medicaid Services (CMS) payments or other transfers of value related to covered products made to health care providers, including physicians, teaching hospitals, and since 2021, advanced practice nurses and physician assistants. PPSA is implemented through the Open Payments National Transparency Program (Open Payments), which collects information about these payments and publishes them online in a searchable database for researchers, law enforcement, journalists, and public use.

We are submitting this generic Paperwork Reduction Act package to conduct formative qualitative research with individuals who are potential health care consumer users of Open Payments. We believe the information gathered from this research will help CMS develop a deeper understanding of the current knowledge, attitudes, practices, and perceived satisfaction of health care consumers relevant to Open Payments.

“Health care consumers” is a large population that nearly equates to “all American adults” and thus for research and outreach purposes, it is important to strategically segment this audience by targeting individuals who are more likely to make a different decision about their health care provider based on data available in Open Payments. Examples of this segmentation include young adults, caregivers, and people actively looking for a new provider. The results of prior research indicated that caregivers, people aged 18 – 34, and those with more education and income may be most likely to show interest in Open Payments. Yet as a government agency that provides health coverage to older and low-income people, CMS wants to reach these groups about Open Payments as well. Thus, the consumer focus group testing detailed in this fast track request includes individuals across all age groups and with varying education levels.

The qualitative research will feature a series of online/telephone (i.e., platform such as Zoom) focus groups that include discussions about:

- The process of finding a health care provider
- Awareness of Open Payments
- Attitudes about financial transparency in health care
- Attitudes about the concept of Open Payments and perceived barriers for its use
- Other uses for the information in Open Payments
- Message testing for Open Payments materials
- Motivators for using Open Payments

Given the range of topics to be covered, there will be two versions of the moderator guide, versions A and B. The only difference between the guides is that Guide A includes the "Open Payments information use" section that asks participants for their reaction to an Open

Payments database search result screen, and Guide B includes a “message testing” section instead. Half of the groups will use each guide (10 groups each), ensuring a balance of the core segments (e.g., education, age).

Benefits of the focus group testing include both gathering a general understanding about health care consumers’ perceptions about Open Payments (its purpose, value to them, and assumed barriers and motivators for its use) and testing specific language in messages that will be used for program outreach with health care consumers. The results of the research will be used by CMS to encourage people to explore the Open Payments database and use the information they find to inform their health care.

The focus groups will be led by a trained facilitator, and will have two additional observers for transcription and note taking purposes. An analysis of the notes and transcripts will be used to develop key themes and a report will be prepared that describes findings, including quotes to highlight key points, and offers specific recommendations.

The information collected through the focus group research is qualitative in nature. The data collection will not include statistical analysis, nor will it be shared publicly. There is no potential for controversy around the data collected, and it will not be used to set any policy.

DESCRIPTION OF RESPONDENTS:

The participants in this focus group research will include individuals 18 – 23 years of age (younger adults out of high school); people 24 – 40 years of age (childbearing age); people 41 – 64 years of age (adults); people 65 years of age and older (older adults); and people in any of these age groups who consider themselves to be caregivers of another person. Each of these participant categories will include groups with people who are seeking a new provider and groups with people who are not seeking a new provider. Groups will be segmented by education (high school or less and some college or more). Twenty focus groups will be conducted with a total of 120 potential Open Payments users.

With an understanding that younger and more educated people were shown to exhibit more interest in the Open Payments database, more of these groups are included in the segmentation of audiences in the table below. However, recognizing the importance of gathering information from all groups, we have included older and less educated groups as well. The breakdown of groups by education level is 13 groups of “college graduate or more” participants versus 7 groups of “high school, some college, or less” participants. Similarly, there are 8 groups of people 40 or younger versus 4 groups of people 41 or older. Caregiver groups will include people of any age caring for a child or other adult. Only one person per household will be eligible to participate in this study.

	18-23 ("Out of HS)	24-40 ("Childbearing")	41-64 ("Adults")	65+ ("Older Adults")	Any age
Not actively seeking new provider	1 HS, some college< group 2 College grad+ group	1 HS, some college< group 2 College grad+ groups	1 HS, some college< group	1 College grad+ group	
Seeking new provider	1 HS, some college< group 2 College grad+ groups	1 HS, some college< group 2 College grad+ group	1 College grad+ group	1 HS, some college< group	
Caregivers					1 HS< group 3 College+ groups

Recruitment will include a mix of:

- Gender
- Race/ethnicity
- Geographic location
- Self-reported urbanicity of community (urban, suburban, rural)

TYPE OF COLLECTION: (Check one)

☐ Customer Comment Card/Complaint Form
☐ Usability Testing (e.g., Website or Software)
☒ Focus Group

☐ Customer Satisfaction Survey
☐ Small Discussion Group
☐ Other: _____

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: _____ [For CPI to sign]

To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? ☐ Yes ☒ No
2. If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974? ☐ Yes ☒ No
3. If Yes, has an up-to-date System of Records Notice (SORN) been published? ☐ Yes ☒ No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? ☒ Yes ☐ No [\$100 incentive payments to focus group participants]

Participating in a 90-minute focus group requires a considerable investment of personal time with the potential for inconvenience to the respondent. Potential participants may be juggling multiple priorities such as work, family obligations, or caregiving responsibilities and can best be enticed to participate in focus groups by offering a nominal token of appreciation. Data quality depends on being able to recruit engaged respondents who are willing to spend time and share their perspectives with the interviewer. The study team feels that anything less than \$100 for focus group participants is likely to significantly hamper recruitment and would not be reflective of the level of appreciation warranted by the respondent's contribution to the study aims.

BURDEN HOURS

Category of Respondent	No. of Respondents	Participation Time (hours)	Burden (hours)
Health Care Consumers Screening	240	5/60	20 hours
Health Care Consumer Focus Group Participants	120	90/60	180 hours
Totals			200 hours

FEDERAL COST:

The estimated annual cost to the Federal government is \$82,000. This will be a one-time cost.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?
☐ Yes ☒ No

If the answer is yes, please provide a description of both below (or attach the sampling plan)?

If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

Participants will be recruited in partnership with a third-party professional recruitment firm that will invite people from their existing lists and conduct additional outreach as needed (e.g., social media, online advertising, college campus outreach). Participants will review and sign an informed consent form before participating. We will recruit 8 participants per group to account for attrition (total of 160). Aggregated details about participant demographics (e.g., race/ethnicity, geographic location) will be included in the final report. Contact information used to communicate with potential respondents is kept as part of the recruitment firm's files, are never connected to the research data, and are never shared with the research team or CMS.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
 - ☒ [X] Web-based or other forms of Social Media
 - ☒ [x] Telephone
 - ☐ [] In-person
 - ☐ [] Mail
 - ☐ [] Other, Explain
2. Will interviewers or facilitators be used? ☒ [x] Yes ☐ [] No

Please make sure that all instruments, instructions, and scripts are submitted with the request.

Attachments:

- Recruitment Guide
- Focus Group Consent Form
- Moderator Guides A and B
- Open Payments Database Example
- Open Payments Consumer Fact Sheet