

Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB Control Number: 0938-1185)

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

PURPOSE:

Under the Physician Payments Sunshine Act, 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 gather qualitative feedback from health care providers. 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 providers relevant to Open Payments.

Health care providers will include physicians, physician assistants, nurse practitioners, and advanced practice nurses such as clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives. Providers will be recruited from a mix of geographic locations.

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

- Awareness of Open Payments
- Attitudes about financial transparency in health care
- Attitudes about the concept of Open Payments
- Barriers and motivators for checking Open Payments data
- Perceived impact of Open Payments on providers' practices
- Perceived impact of Open Payments on relationship with industry
- Message testing for Open Payments materials

Benefits of the qualitative testing include both gathering a general understanding of health care providers' 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 providers. The results will be used by CMS to encourage providers to review their data in the Open Payments system.

The interviews will be conducted by a trained facilitator and will have an additional observer for note taking purposes. The interviews will be recorded and transcribed. 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 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 will include health care providers including physicians, physician assistants, and advanced practice nurses such as nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives. Providers will be separated into two categories – those who consider themselves to be primary care providers and those who are specialists. This distinction recognizes that provider relationships with the pharmaceutical and medical device industry likely differs for providers in these two categories.

In addition, we will include a group of administrative representatives from teaching hospitals that Open Payments records show have verified their Open Payments data within the last year.

In total, we will interview 16 physicians and 16 physician assistants/advanced practice nurses who did not check their Open Payments data in the past year, 10 physicians who checked their Open Payments data in the past year, and 6 representatives from teaching hospitals that checked their data in the past year.

The following table presents the segmentation for all audiences. The assumption is that there will be more interest and interaction with the Open Payments database among specialist providers because they receive more payments on average. Thus, we have included more specialists than primary care providers.

	Primary Care	Specialist
Physicians	6	10
PAs/Advanced Practice Nurses	6	10
Physicians who checked data in last year	10	
Teaching hospitals that checked data in last year	6	
TOTAL	48	

Provider recruitment will include a mix of:

- Physician specialties
- Non-physician health care provider types (PAs, Nurse Practitioners, etc.)
- Setting: Private practice, public health clinic, hospital-based, and mobile or home-care (emphasis on private practice)
- Geographic location

TYPE OF COLLECTION: (Check one)

- | | |
|--|---|
| ☐ Customer Comment Card/Complaint Form | ☐ Customer Satisfaction Survey |
| ☐ Usability Testing (e.g., Website or Software) | ☐ Small Discussion Group |
| ☐ Focus Group | ☒ Other: <u>Individual Interviews</u> |

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.

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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 [\$150 for primary care; \$225 for specialists; \$75 for teaching hospital administrators]

Participating in a 45-minute interview requires a considerable investment of time and potential inconvenience to respondents, particularly health care providers. Physicians and other providers have to juggle their scheduled patients, emergency patient visits, and other professional obligations. As a result, physicians often decline to participate. Data quality depends on being able to recruit engaged respondents who are willing to spend time and share their perspectives with the interviewer. To encourage participation and engagement in the process, tokens of appreciation must be high enough to ameliorate the burden placed on

respondents with respect to their time, as well as provide enough motivation to participate in the study rather than another activity. The study team feels that anything less than \$150 for primary care, \$225 for specialists, and \$75 for teaching hospital administrators 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 Provider/Hospital Administrator: Screening	90	5/60	8 hours
Health Care Provider/Hospital Administrator: Interview Participation	48	45/60	36 hours
Totals			44 hours

FEDERAL COST:

The estimated annual cost to the Federal government is \$58,000. This is 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?

[x] Yes [x] 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 through several methods:

- YES (participants who have checked data in Open Payments): A random selection of providers and teaching hospital representatives who have checked their data in the last year will be pulled from the Open Payments database. These providers will receive an email inviting them to participate in an interview and referring them to a third-party recruitment firm for screening and scheduling.
- NO (all other participants): Participants will be recruited by a third-party recruitment firm using their existing database. CMS also may work with professional organizations to promote the study with their members via their communication channels (e.g., social media, email, newsletter). Interested providers will contact the recruitment firm directly for screening and scheduling,

Participants will review and sign an informed consent form before participating. We will screen 90 providers to account for attrition (total of 48 interviewees). Aggregated details about participant characteristics (provider type, medical specialty, geographic location) will be included in the final report. Some personally identifiable information will be managed and securely stored by a third-party specialty recruitment firm (e.g., phone numbers, email addresses, names) as part of the screening process, but will never be shared with the research team or CMS and will only be retained until the recruitment and interviews are completed.

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 Guides
- Interview Consent Form
- Interview Guides A and B
- Open Payments Database Example
- Open Payments Fact Sheet for Providers