Supporting Statement A

Centers for Medicare & Medicaid Services (CMS)
Office of Burden Reduction and Health Informatics (OBRHI)
Data Collection to Support CMS Burden Reduction and Health Informatics Efforts
(OMB# 0938-New; CMS-10830)

CMS seeks to establish a generic clearance entitled *Data Collection to Support CMS Burden Reduction and Health Informatics Efforts.* This generic clearance will be used to permit quick turnaround data collection projects that support CMS efforts to infuse customer perspectives, apply innovative solutions, advance standards and information technology (IT) interoperability, advance health equity, and respond to emerging priorities. CMS will utilize a range of methodologies through this generic clearance including surveys, focus groups, stakeholder/key informant interviews, cognitive interviews, site visits, and usability testing.

A. Justification

1. Need and Legal Basis

The CMS Office of Burden Reduction & Health Informatics (OBRHI) was established to serve as a focal point and champion for burden reduction, national standards and interoperability, and to engage internal and external customers to inform solutions. In support of this work, we solicit stakeholder input and feedback to better support the populations we serve and those who assist with delivering healthcare services. OBRHI develops and implements solutions to clarify, streamline, and modernize CMS policies and regulations to promote equitable, accessible, efficient, and effective healthcare delivery. OBRHI supports CMS efforts to improve the day-to-day experience in the healthcare system by furthering interoperability, driving national standards, and improving access to health information for Medicare and Medicaid beneficiaries, Marketplace consumers, providers, and payers.

Improving quality and population health for all requires an understanding of the wholistic customer experience. OBRHI will utilize this generic clearance to engage with the public to seek insights, and ensure those perspectives are reflected in CMS policy and operations. OBRHI curates these insights to drive action across the healthcare enterprise.

OBRHI conducts data-driven research to understand, measure, and identify opportunities to reduce, where appropriate, regulatory burden and to improve access to quality, affordable healthcare. As part of its efforts, OBRHI engages a broad range of stakeholders, including patients and their families, providers, consumer advocates, and health care professional associations, to understand their experiences with CMS regulations, particularly how existing and proposed CMS regulations impact the experience of healthcare.

OBRHI seeks to establish this generic clearance to utilize standardized data collection methods that may be needed to support specific projects, often with quick turnaround deadlines, to gather timely stakeholder perspectives, which are necessary to inform CMS efforts on emerging issues such as responding to a public health emergency. These data collections support CMS cross-

cutting initiatives to elevate stakeholder voices through active engagement and using data to drive decision-making.

Data collections conducted under this clearance will support CMS efforts to implement Executive Order 14058[1], which directs agencies to prioritize efforts to improve service delivery and customer experience. OBRHI plays an important role in CMS efforts to improve the customer experience by infusing customer perspectives across the Agency and developing innovative solutions that reduce customer burden. Data collections under this generic clearance will allow OBRHI to support CMS Agency-wide efforts to improve service delivery by reducing administrative burden and implementing innovative solutions as outlined as outlined in OMB Memorandum M-22-10: Improving Access to Public Benefits Programs Through the Paperwork Reduction Act.

OBRHI is also supporting CMS efforts to advance health equity by assisting CMS programs in understanding and addressing inequities as directed by Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.[2] CMS and OBRHI are committed to advancing health equity by understanding and addressing the burdens, disparities, barriers, and challenges people experience in our nation's health system. For example, CMS is seeking to better incorporate the perspectives of individuals with lived experiences, safety net providers, and community-based organizations. Data collections conducted through this generic clearance will allow CMS to better understand how changes to CMS regulations and policies could improve equity.

2. Purpose and Use of Information Collection

Data collected under this generic clearance will support CMS and OBRHI efforts to reduce the burden of CMS regulations, sub-regulations, and policies as well as increasing the use of digital health tools to improve the customer experience. Obtaining feedback from CMS stakeholders is a core component of OBRHI's work to assist CMS in improving service delivery.

All data collections submitted under this generic clearance will meet the following conditions:

- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the Agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions[3];
- Information gathered will yield qualitative information;

[1] E.O. 14058: Transforming Federal Customer Experience and Service Delivery To Rebuild Trust in Government, 86 FR 71357 (December 13, 2021). https://www.federalregister.gov/documents/2021/12/16/2021-27380/transforming-federal-customer-experience-and-service-delivery-to-rebuild-trust-in-government

[2] E.O. 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 FR 7009 (January 25, 2021). https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government

[3] As defined in OMB and HHS Information Quality Guidelines, "influential" means that "an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions."

- The collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study;
- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any 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 near future; and
- Collection of personally identifiable information (PII) will be limited to collecting contact information that is needed for scheduling of interviews and payment of any incentives and all PII will be destroyed upon completion of the data collection.

To obtain approval for a collection that meets the conditions of this generic clearance, a standardized form will be submitted to OMB along with supporting documentation (e.g., data collection instruments).

OBRHI anticipates using a wide range of data collection methods that will be selected depending on the specific goals and the target audience. These data collection methods include, but are not limited to:

- Stakeholder/Key Informant Interviews: One-on-one interviews with key stakeholders, typically conducted using a semi-structured interview protocol.
- Focus Groups: Interviews conducted with a small group of individuals, led by a moderator typically following a semi-structured protocol established in a moderator's guide.
- Surveys & Forms: Surveys administered to non-probability groups of individuals, including surveys used to collect feedback on trainings. This can also include requesting that participants complete a standardized questionnaire prior to participating in an unstructured interview or listening session.
- Site Visits: Include a combination of direct observation and qualitative interviews to better understand observations.
- Usability Testing: Used to evaluate a product or service that combines direct observation of an individual using the product or service and supplementing this with qualitative interviews. This can also include utilizing eye-tracking technology to better understand how the visual design impacts the individual's usage of the product or service.
- Cognitive Testing: Qualitative research method used to evaluate survey questions prior to full-scale survey administration by asking supplemental probes to identify the respondent's understanding of the survey question.

All of OBRHI's data collection approaches may be conducted virtually (online, videoconference, etc.) or in-person.

3. Use of Information Technology

OBRHI anticipates that most of the data collections under this clearance will utilize a variety of information technology (IT) resources. The COVID-19 pandemic has rapidly increased the use of virtual interviewing conducted using videoconferencing software (e.g., Zoom). We also anticipate utilizing online data collection tools to support the screening of potential qualitative research participants to determine their eligibility. Finally, we anticipate that the majority of surveys will be web surveys that could be supplemented with other data collection modes to improve response rates and representativeness.

4. Duplication of Efforts

Given OBRHI's focus on burden reduction, OBRHI has conducted a thorough review of existing CMS data collections to ensure that its efforts do not duplicate other data collections. While CMS has other existing generic clearances, the terms of these clearances limit OBRHI's ability to utilize these existing mechanisms. For example, CMS's Generic Social Marketing & Consumer Testing Research (OMB No. 0938-1247) limits surveys to items in an existing item bank. Due to these limitations, OBRHI is seeking to establish this generic clearance to better meet its needs. Prior to beginning data collection, OBRHI will coordinate with other CMS centers and offices to ensure that its research efforts are not duplicative.

5. Small Businesses

Some data collections under this clearance may involve small businesses, such as a smaller physician practices or clinics. Obtaining feedback from these types of healthcare providers is critical to inform OBRHI's efforts to assess whether CMS policies have an undue burden on these types of smaller providers. In instances where OBRHI collects information from small businesses, it will design the data collection effort to limit the burden imposed on small businesses.

6. Less Frequent Collection

Data collections conducted under this clearance are necessary to inform CMS efforts to reduce stakeholder burden and support the uptake of health informatics. Conducting data collections less frequently will impede CMS' ability to support evidence-based decision-making about ways that CMS can improve its work.

7. Special Circumstances

Explain any special circumstances that would cause an information collection to be conducted in a manner.

- requiring respondents to report information to the agency more often than quarterly;

- requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;

- requiring respondents to submit more than an original and two copies of any document;

- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;

- in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,

- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;

- that includes a pledge of confidentiality that is not supported by authority established in statue or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect die information's confidentiality to the extent permitted by law.

There are no special circumstances associated with this information collection request, and it fully complies with 5 CFR § 1320.5.

8. Federal Register / Outside Consultation

On October 28, 2022, CMS published a 60-day Federal Register notice (87 FR 65207) seeking public comment about this data collection. CMS received four comments in response to the Federal Register Notice; however, three of the comments received were non-substantive. Two comments referred to other CMS federal register notices. One comment referred to data collections by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA).

One commenter sought clarification about the type of data that CMS was seeking to collect, data collection methodology, and frequency of data collection. As noted in this supporting statement, CMS will submit documentation to OMB prior to each individual data collection, including specifying the information being collected and the proposed methodology. CMS anticipates that most data collections conducted under this generic clearance will be one-time data collections.

The 30-day notice published on January 27, 2023 (88 FR 5359)

9. Payments/Gifts to Respondents

It is important to offer incentives sufficient to attract the full range of needed respondent types for data collection projects. Inadequate respondent recruitment can hinder a research project.

Given the focus on health equity, many data collections will focus on hard-to-reach populations, such as individuals in rural communities and healthcare providers. Incentives have been shown to improve the quality and efficiency of research in a number of ways, including reducing non-response bias, improving participation by those in hard-to-reach groups, and increasing the

efficiency and cost-effectiveness of research (e.g., David & Ware, 2014; Singer & Ye, 2013; Stewart & Shamdasani, 2015). These effects have also been demonstrated in surveys of healthcare professionals, a key population of interest for data collections conducted under this generic clearance (Cho, Johnson, and VanGeest, 2013). A recent study assessing the incentive amount necessary to recruit physicians to participate in research studies found that to have a 75% participation rate for a one-hour qualitative research project, researchers would need to offer between $218 and $344 depending on the participant's medical specialty (Clement and Claeys, 2019).

OMB's guidance[4] on offering incentives to respondents notes that the proposed incentive amount should factor in the impact of the incentive on data quality; improved coverage of specialized respondents, rare groups, or minority populations; and reduced survey costs. OMB's guidance also notes the importance of considering experience, including findings from similar studies.

Requests and justification for incentives will be included in each individual collection submission.

References

Cho YI, Johnson TP, VanGeest JB. Enhancing surveys of health care professionals: a meta-analysis of techniques to improve response. *Eval Health Prof*. 2013;36(3):382-407. doi:10.1177/0163278713496425

Clement, Lynn and Claeys, Chris. What's fair? The fair market value dilemma in health care research. Quirk's Market Research Review. April-May, 2019.

David MC and Ware RS (2014). Meta-analysis of randomized controlled trials supports the use of incentives for inducing response to electronic health surveys. J Clin Epidem, 67(11), 1210-1221.

Singer E and Ye C (2013). The use and effects of incentives in surveys. Ann Am Acad Pol Soc Sci, 645(1): 112-141.

Stewart DW and Shamdasani PN (2015). Focus Groups: Theory & Practice, 3rd Edition. Los Angeles: Sage.

10. Confidentiality

All data collected under this clearance will only be used for statistical purposes as defined by 44 USC § 3561(12)[5]. The confidentiality of data collected for statistical purposes is protected by Foundations for Evidence-Based Policymaking Act of 2018 (44 USC § 3572).

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[4] Office of Management and Budget. (2016, October). *Questions and Answers When Designing Surveys for Information Collections*. Retrieved August 18, 2022, from https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/assets/OMB/inforeg/pmc_survey_guidance_2006.pdf

[5] 44 USC § 3561(12) states, "The term "statistical purpose"— (A) means the description, estimation, or analysis of the characteristics of groups, without identifying the individuals or organizations that comprise such groups; and (B) includes the development, implementation, or maintenance of methods, technical or administrative procedures, or information resources that support the purposes described in subparagraph (A)."

Further, the confidentiality of this data is assured by the Privacy Act of 1974 (5 USC § 552a and 45 CFR Part 5b).

11. Sensitive Questions

The majority of data collections conducted under this clearance will not involve sensitive questions; however, some data collections with patients or beneficiaries may include questions that could be considered sensitive. For example, some data collections may ask participants to discuss their medical history. Additionally, to support CMS efforts to advance health equity, data collections may collect information about a participant's sexual or gender identity.

In instances where OBRHI seeks to collect more sensitive information, the data collection methodology will be designed to protect respondent confidentiality. Further, OBRHI will clearly explain to participants why the collection of this information is necessary and remind participants of the confidentiality of their responses.

12. Burden Estimates

OBRHI will use a variety of data collection methods under this generic clearance. The table below outlines the proposed burden associated with this generic clearance totaling 5,034 hours.

Type of Data Collection	Num. of Respondents	Hours per Response	Total Hours
Qualitative Interview (Stakeholder Interviews, Focus Groups, Usability Testing, Cognitive Interviews)	600	1.5	900
Surveys & Forms	15,000	0.25	3,750
Site Visits	48	8	384
TOTAL	**15,648**		**5,034**

Under this clearance, OBRHI will collect information from a broad range of CMS stakeholders including healthcare providers, administrative and support personnel, as well as patients and caregivers.

To accurately estimate the cost associated with the requested burden hours, CMS estimates that data collections with patients and caregivers will total approximately 1,000 hours (approximately 20% of the requested burden hours). The remaining burden hours (4,034) will be divided between physicians, physician assistants and nurse practitioners, and other management/support staff for healthcare providers.

The table below shows the calculations for the estimated costs associated with this generic clearance. Hourly wages were estimated based on data from the Occupational Employment and Wage Statistics published by the Bureau of Labor Statistics (BLS). All wages are estimated as of May 2021, which is the most recent data available at the time. Each of the three main audiences were mapped to a BLS Occupation Code. The following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage. We are adjusting our employee hourly wage estimates by a factor of 100 percent because fringe benefits and overhead costs vary significantly from employer to employer, and because methods

of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

The hourly rate for physicians was estimated using the mean hourly wage of all physicians. CMS has estimated the hourly rate for physician assistants and nurse practitioners based on the mean hourly rate for physician assistants because the two groups have very similar hourly rates with physician assistants having a slightly higher rate. The costs for office managers and administrative personnel are estimated based on the Medical and Health Services Managers Occupation Code. Costs for patients and caregivers is based on the mean hourly wage of all occupations.

The total estimated burden cost over the 3-year clearance is $749,695.66

Population	**BLS Occupation Code**	**Estimated Burden Hours**	**Mean Hourly Wage**	**Hourly Wage + Fringe and Overhead**	**Total Cost**
Healthcare Providers	Physicians (29-1210)	2,017	$121.38	$242.76	$489,646.92
Healthcare Providers	Physician Assistants (29-1071)	1,000	$57.43	$114.86	$114,860.00
Office Managers and Administrative Personnel	Medical and Health Services Managers (11-9111)	1,017	$57.61	$115.22	$117,178.74
Patients and Caregivers	All Occupations (00-0000)	1,000	$28.01	**	$28,010.00
TOTAL		**5,034**			**$749,695.66**

**In this instance we have not accounted for fringe and overhead.

13. Capital Cost

There is no annual capital or maintenance costs to the respondent resulting from this collection of information.

14. Cost to Federal Government

Costs will be determined on an individual project basis and will be included in the ICR provided to OMB for each project to be conducted.

15. Changes to Burden

This is a new data collection.

16. Publication/Tabulation Dates

No attempt will be made to generalize the findings from data collections conducted under this clearance to be nationally representative or statistically valid. Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. Findings will be used for general service improvement.

Insights gleaned from qualitative customer research may be presented publicly in the format of a conceptual user persona or customer journey map. Publicly available journey maps will include specific language to contextualize their use. This language will be based on this model language:

> *What should I know about journey maps?*
>
> *Journey maps are living documents—continually refined and revisited. There is never a "final" version, and these maps are meant to serve as a summary of the voices of actual customers of U.S. Government services. A map may not precisely document the way a Government program is meant to be navigated, accessed, or used. It might not capture every government program or resource available to a customer segment. However, it is the product of a qualitative research approach to gather insights from customers' actual experiences. These findings can help us to identify areas for high-impact improvements across delivery channels and organizational silos.*

Although the Agency does not intend to publish its findings, the Agency may receive requests to release the information (e.g., congressional inquiry, Freedom of Information Act requests). The Agency will disseminate the findings when appropriate, strictly following the Agency's "Guidelines for Ensuring the Quality of Information Disseminated to the Public" and will include specific discussion of the limitation of the qualitative results discussed above.

17. Expiration Dates

The expiration date will be displayed.

18. Certification Statement

These activities comply with the requirements in 5 CFR § 1320.9.