

**Supporting Statement A**  
**For Revision of Currently Approved Collection:**  
**Medicare Current Beneficiary Survey (MCBS)**

Contact Information:

William S. Long  
Contracting Officer's Representative, Medicare Current Beneficiary Survey  
Office of Enterprise Data and Analytics (OEDA)/CMS  
7500 Security Boulevard, Mail Stop Mailstop B2-04-12  
Baltimore, MD 21244  
(410) 786-7927  
[william.long@cms.hhs.gov](mailto:william.long@cms.hhs.gov) (410) 786-5515 (fax)

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## Background

CMS is the largest single payer of health care in the United States. CMS plays a direct or indirect role in administering health insurance coverage for more than 120 million people across the Medicare, Medicaid, CHIP, and Exchange populations. A critical aim for CMS is to be an effective steward, major force, and trustworthy partner in supporting innovative approaches to improving quality, accessibility, and affordability in healthcare. CMS also aims to put patients first in the delivery of their health care needs.

CMS activities result in substantial data generation. Although administrative data are a critical resource for CMS and its partners, there remains an important need for self-reported data to obtain information that is not captured through other CMS operations. For example, a Medicare beneficiary's satisfaction with, access to, and quality of care are important pieces of information that can only be captured by obtaining the beneficiary's unique perspective. In addition, information on beneficiary insurance coverage and payments from non-Medicare sources (including beneficiary out-of-pocket spending) are collected by surveying beneficiaries because these data are currently not available to CMS from administrative sources. These survey-collected data elements, combined with CMS administrative data, complete the picture of a beneficiary's health care experience and provide a vital component in the development and evaluation of models and analysis conducted by CMS.

The MCBS is the most comprehensive and complete survey available on the Medicare population and is essential in capturing data not otherwise collected through CMS operations. The MCBS is a nationally-representative, longitudinal survey of Medicare beneficiaries that is sponsored by CMS and directed by the Office of Enterprise Data and Analytics (OEDA). The survey is conducted through a contract with NORC at the University of Chicago (NORC). Most interviews were traditionally conducted in-person in households and facilities using computer-assisted personal interviewing (CAPI). Due to the COVID-19 pandemic, data collection switched to phone-only interviews in March 2020 and throughout most of 2021 with a gradual return to in-person interviewing beginning in November 2021. MCBS data collection will continue to include both in-person and phone interviewing to reduce costs and continue addressing pandemic safety protocols, recognizing that some in-person interviewing is necessary to improve response rates and collect complex cost and utilization information while also retaining the benefit of reduced interviewer costs by collecting some data by phone. The respondent burden is the same regardless of mode of interview.

The MCBS has been continuously fielded for over 30 years, encompassing over 1.2 million interviews with more than 140,000 survey participants. The MCBS respondents are interviewed up to three times per year over a four-year period; the rounds are referred to as Fall, Winter, and Summer. New survey participants always join in the Fall round; this panel's first round includes a Baseline interview and establishes a recall boundary for the next interview (the interview reference period is since the date of the previous interview). For the next 10 rounds (referred to as Continuing interviews), cost and utilization information and other health related questionnaire sections are administered to the panel. The panel exits the survey after its 11<sup>th</sup> interview which occurs in the Winter round.

The survey captures beneficiary information whether aged or disabled, living in the community or facility, or serviced by managed care or fee-for-service. Questions are asked about enrollees'

health care use, charges, insurance coverage, and payments over time. Respondents are asked about their sources of health care coverage and payment, their demographic and housing characteristics, their health and work history, and their experiences and perceptions of quality with their health care system. Data produced as part of the MCBS are enhanced with CMS administrative data (e.g. fee-for-service claims, prescription drug event data, enrollment data, Medicaid payments and eligibility, and Medicare Advantage encounter records) to provide users with more accurate and complete estimates of total health care costs and utilization.

The primary goals of the MCBS are to:

- provide information on the Medicare beneficiary population that is not available in CMS administrative data and that is uniquely suited to evaluate or report on key outcomes and characteristics associated with beneficiaries treated in innovative payment and service delivery models;
- determine expenditures and sources of payment for all services (including services not covered by Medicare) used by Medicare beneficiaries, including copayments, deductibles, and non-covered services;
- ascertain all types of health insurance coverage among Medicare beneficiaries (e.g., Medigap coverage, retiree coverage) and relate this coverage to payment for specific services; and
- track changes in key beneficiary metrics over time, such as changes in health and functional status, spending down to Medicaid eligibility, access and satisfaction with Medicare programs and providers, and fluctuations in out-of-pocket spending.

The MCBS has been at the forefront of in-person survey collection and data processing, most notably as one of the first surveys to successfully 1) implement a computer assisted personal interview (CAPI) and 2) match survey and claims data to adjust and correct for underreporting in survey reported health care utilization. The CMS vision for the MCBS is to continue to provide unique, high-quality and high-value data in a timely manner, continue to break ground in innovative, efficient and analytically powerful new areas of survey data administration, design and development, and to increase the survey's ability to develop, monitor, assess and evaluate the impact of CMS care delivery and payment models. To succeed in these areas, CMS aims to:

- capture high-value, unbiased, minimally burdensome, self-reported content that is multipurpose in use;
- improve the integration of existing and new sources of administrative data with MCBS survey collected data;
- develop and implement more efficient, cost-effective, accurate and innovative data collection strategies when possible; and
- enhance the understanding, usefulness, and promotion of MCBS through the dissemination of user tools and key scientific findings based on MCBS data.

This is a request for revision to the Medicare Current Beneficiary Survey's (MCBS) current OMB clearance (OMB No. 0938-0568, Ex. Date 2/29/2024). The MCBS is the most comprehensive and complete survey available on the Medicare population and is essential in capturing data not otherwise collected through CMS operations.

The purpose of this revision is to seek approval for CMS to add new items to the MCBS Community questionnaires beginning in 2023, which will extend the current collection for an additional three years as a result. The new items cover important topics including:

- Medicare beneficiaries’ use of the Medicare Savings Program (MSP)
- Beneficiary knowledge of their right to appeal or file a complaint under the Medicare program,
- Beneficiary use of cannabidiol (CBD) to manage pain,
- Prevalence of bowel incontinence,
- Prevalence of oral health issues,
- Health equity –perceived discrimination by health care providers, and
- Health equity – expanded socio-demographic items to include religious affiliation, sexual orientation, and gender identity.

This clearance request also documents deletions to the Community and Facility instruments related to COVID-19 content that is no longer relevant for administration. The estimated respondent burden is also updated to reflect the impact of the additional content and the offset by the deletion of some COVID-19 content. New respondent materials intended to increase understanding of the survey and thus, improve participation, are also included in this request.

## **A. Justification**

### ***A1. Circumstances Making the Collection of Information Necessary***

While the administrative data available to CMS via claims records is rich in its breadth and accuracy, it does not contain important information that can only be obtained by interviewing beneficiaries. In particular, the current administrative information collected by CMS does not provide the complete picture needed for CMS to evaluate its programs and comply with legislative mandates found in both:

- a. Section 1115A of the Social Security Act, as established by Section 3021 of the Affordable Care Act (ACA) of 2010; and
- b. Section 723 of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003.

The MCBS supports CMS’ program evaluation and legislative mandate compliance by providing data to determine expenditures and sources of payment for all services used by Medicare beneficiaries, including co-payments, deductibles, and non-covered services; to ascertain all types of health insurance coverage and relate coverage to sources of payment; and to trace processes over time, such as changes in health status and “spending down” to Medicaid eligibility and the impacts of program changes, satisfaction with care, and usual source of care. These unique design features of the MCBS enable it to support a variety of CMS functional areas. For example, the MCBS is used by CMS analysts to assess the potential number of beneficiaries eligible for proposed new care and payment models, their Baseline utilization and patterns of usual care, and the factors that help determine when and where beneficiaries seek care. In addition, the MCBS panel design provides essential longitudinal data to measure change over time. Last, a unique feature of the MCBS -- the capacity to follow individuals from the community into and out of nursing homes and hospitals-- provides critical data including the

opportunity to estimate the total cost of episodes of illness and level and type of system interventions including home health care, as well as the care transitions that occur across the various care providers.

## ***A2. Purpose and Use of Information Collection***

The MCBS continues to provide unique insight into the Medicare program and helps both CMS and external stakeholders better understand and evaluate the impact of existing programs and significant new policy initiatives. In the past, MCBS data have been used to assess potential changes to the Medicare program. For example, the MCBS was instrumental in supporting the development and implementation of the Medicare prescription drug benefit by providing a means to evaluate prescription drug costs and out-of-pocket burden for these drugs to Medicare beneficiaries.

Moving forward, the MCBS will continue to play a critical role in the monitoring and evaluation of Medicare, with an emphasis on supporting CMS efforts to test innovative payment and service delivery models' ability to reduce costs and improve quality. For example, the longitudinal and comprehensive nature of the MCBS provides the opportunity for both pre/post and observational studies (with a control and comparison group) for beneficiaries involved with CMS models or other CMS programs. Other areas that can only be captured by using survey data along with the CMS administrative data include changes to Part D coverage, changes to cost-sharing and premiums, and the use and knowledge of existing and new Medicare-covered preventive services.

MCBS data will also continue to be used by CMS to assess the impact of major policy innovations and health care reform on Medicare beneficiaries (pre and post implementation). MCBS data users continue to monitor delivery of services, sources of payment for Medicare covered and non-covered services, beneficiary cost sharing and financial protection, and satisfaction with and the access to health care services, and integration of patient care. Analysts can relate the dynamics of future aging patterns to age-specific rates of use of health care services. MCBS data also allow accurate measurement of total health care expenditures for enrollees and changes in private health insurance benefits (including long-term care insurance). The capacity to follow individuals into and out of nursing homes and hospitals provides analysts the opportunity to estimate the total cost of episodes of illness and level and type of system interventions including home health care.

Analysts can assess the aggregate cost of short stays and long stays in nursing homes, and of combined hospital/nursing home stays. In addition, the MCBS data can be used to forecast the need and settings for selected chronic disease care and long-term care services by examining trends in the use of health care services, linked with morbidity, disability and mortality data.

The comprehensive nature of the MCBS makes its data appealing to a broad spectrum of users. In addition to CMS use, the MCBS consistently provides value and unique data to external users, as demonstrated by more than 4,500 research articles and citations using the MCBS to date, over 250 MCBS Limited Data Set (LDS) files purchased and shipped to researchers each year, and over 120 MCBS Public Use File (PUF) downloads per month. MCBS survey data are also vital in the production of highly regarded publications, including the Medicare Payment Advisory Commission's annual data book "Health Care Spending and the Medicare Program", the Federal

Interagency Forum on Aging Related Statistics' chartbook "Older Americans: Key Indicators of Well-Being", and CMS' Annual Trustees Report.

- Within CMS. Survey results have been and will continue to be used by various organizations within the CMS. CMS analysts have frequently used the data collected by the MCBS for a variety of purposes, including to assess the potential number of beneficiaries eligible for proposed new care and payment models, their utilization and patterns of usual care over time, and the decisional factors that help determine when and where beneficiaries seek care.

The MCBS is used by the CMS Office of the Actuary to track trends in out-of-pocket spending and monitor Medicare supplemental insurance (Medigap) and is a major source of information for the annual Trustees' Report. MCBS data have also been used to track beneficiary's knowledge and sources of information about Medicare, especially following the implementation of a new program or services (e.g. Part D, "Welcome to Medicare" benefits, etc.). Self-reported MCBS data on immunizations and preventive screenings are used to track whether CMS is meeting population health objectives.

Analysis of the facility component also allows CMS to examine expenditures that are covered by Medicaid, the shifts between private pay and Medicaid, and the cost implications for both Medicare and Medicaid in the areas of spending down assets and spousal impoverishment.

In other examples, the CMS Office of Communication uses the MCBS to track beneficiaries' knowledge and sources of information about Medicare as well as population out of pocket spending in the Plan Finder tool. Within CMS, there is also collaboration with the CMS Office of Minority Health to improve MCBS survey measures used to track social risk factors and health disparities.

CMS provides an annual annotated bibliography that includes research using MCBS data. This is a helpful resource to CMS staff, other government analysts, and the research community at large. The bibliography is available at [CMS MCBS Bibliography](#).

- Other Governmental / quasi-governmental, outside CMS. The MCBS is a major source of information for the Medicare Payment Advisory Commission (MedPAC) to monitor access to health care and beneficiary financial protection. The MCBS data have been routinely included in MedPAC's Annual Reports and data collected by the MCBS have been used both in descriptive statistics and simulation.

The MCBS is also a major source of information for the Government Accountability Office (GAO) to monitor the impact that different types of insurance coverage have on beneficiary health care expenses.

Several other agencies that have developed a partnership in using MCBS data include the Congressional Budget Office, Public Health Service, Centers for Disease Control and Prevention, National Institute of Mental Health, National Institute on Aging, and Advisory Council on Social Security. Foundations such as Kaiser Family Foundation, Robert Wood Johnson, and the Commonwealth Fund also use MCBS data for policy analyses.



- Other researchers. Data are available to academic researchers through data use agreements. Additionally, beginning with data collected in the 2013 Medicare Current Beneficiary Survey (MCBS), a public use file (PUF) and accompanying documentation is available free for download. Topics of other research found in annual bibliographies of MCBS data include chronic disease, effects of Medicare drug coverage, use of preventive services, underuse of medications, hospital readmission, body mass and aging, assistance with activities of daily living, obesity, quality of care, alcohol use, home care, disability trends, treatments for dementia, depression, beneficiary knowledge, informal assistance, use of durable medical equipment, and falls. These are just a few examples of actual uses of MCBS data for policy research; bibliographies by year can be found at [CMS MCBS Bibliography](#).

**Requested Revisions to Currently Approved Collection:**

This is a request to revise the existing MCBS clearance beginning in 2023, which will extend the collection for an additional three years as a result. This revised clearance request includes additions to the Community Baseline and Continuing instruments as well as deletions of COVID-19-specific content from the Community and Facility instruments. New respondent materials intended to increase understanding of the survey and thus, improve participation, are also included in this request and have no impact to respondent burden.

When implemented, the revision to this OMB package will result in a **net decrease** in respondent burden as compared to the current clearance. While the new questions are projected to **add 5.4 minutes** to the Community questionnaire each year starting in 2023, deletions of COVID-19 content will **remove 38 minutes from the Community instrument annually** (13 minutes each Summer and Fall round and 12 minutes in the Winter round). Deleting COVID-19 content from the Facility instrument will also remove **36 minutes from Facility data collection annually** (13 minutes in the Winter and Summer rounds and 10 minutes in the Fall round).

The current OMB clearance projects an annual respondent burden of 54,426 hours. This revision to the clearance reduces the annual respondent burden by 7,746 hours, bringing the total annual respondent burden to 46,680 hours. The changes in estimated annual respondent burden are summarized in Table B-12 (under section A12 below). All of these changes are described below and are referred to in Supporting Statement, Part B as well.

The proposed revisions are described below. Changes that will **increase** respondent burden are summarized in table A-1 by questionnaire section and administration schedule.

**Table A-1: Summary of New Items by Questionnaire Section and Administration Schedule**

Content Request	# of Items	Questionnaire Section	Administration Schedule
Use of Medicare Savings Program (MSP)	2	Beneficiary Knowledge and Decision-Making Questionnaire (KNQ)	Annually, Winter Round
Right to File a Complaint or Appeal	1	Beneficiary Knowledge and Decision-Making Questionnaire (KNQ)	Annually, Winter Round

Content Request	# of Items	Questionnaire Section	Administration Schedule
Use of Cannabidiol (CBD) for Pain Management	1	Chronic Pain Questionnaire (CPQ)	Annually, Summer Round
Bowel Incontinence	5	Health Status and Functioning Questionnaire (HFQ)	Annually, Fall Round
Oral Health	3	Health Status and Functioning Questionnaire (HFQ)	Annually, Fall Round
Health Equity – Perceived Discrimination from Health Providers	8	Satisfaction with Care (SCQ)	Annually, Fall Round
Health Equity – Expanded Socio-Demographic Items to Include Religious Affiliation	2	Demographics and Income Questionnaire (DIQ)	Annually, Fall Round
Health Equity-Expanded Socio-Demographic Items to Include Sexual Orientation and Gender Identity	4	Demographics and Income Questionnaire (DIQ)	Annually, Fall Round

These changes include:

- Add Two Items about Use of the Medicare Savings Program.** The Beneficiary Knowledge and Information Needs Questionnaire (KNQ) section is administered once per year during the Winter round. This revision adds two items to KNQ to measure beneficiary use of the Medicare Savings Program (MSP). The MSP program provides financial support to Medicare beneficiaries who do not qualify for Medicaid. There are four different MSP state-sponsored programs: (1) Qualified Medicare Beneficiary Program (QMB), (2) Specified Low-Income Medicare Beneficiary Program (SLMB), (3) Qualifying Individual Program (QI), and (4) Qualified Disabled and Working Individuals Program. Through these programs, beneficiaries may receive assistance paying for their Medicare premiums. In some cases, MSP may also pay Medicare Part A (Hospital Insurance) and Medicare Part B (Medical Insurance) deductibles, coinsurance, and copayments if the beneficiary meets certain conditions.

Enrollment in the Qualified Medicare Beneficiary program has been found to increase access to outpatient care. One study found that the program decreased cost-related forgone health care provider visits by nearly half<sup>1</sup>. However, the program remains underutilized. Among eligible beneficiaries, only 53% are enrolled in the QMB program, 32% are enrolled in the SLMB program, and 15% are enrolled in the QI program<sup>2</sup>.

Barriers to MSP enrollment vary by beneficiary and by state but are generally attributed

<sup>1</sup> Federman, A. D., Vladeck, B. C., & Siu, A. L. (2005). Avoidance of health care services because of cost: impact of the Medicare savings program. *Health affairs (Project Hope)*, 24(1), 263–270. <https://doi.org/10.1377/hlthaff.24.1.263>

<sup>2</sup> <https://www.macpac.gov/wp-content/uploads/2017/08/Medicare-Savings-Programs-New-Estimates-Continue-to-Show-Many-Eligible-Individuals-Not-Enrolled.pdf>

to lack of knowledge about the program, administrative complexity of enrolling, stigma, cultural and language barriers, and fears about the estate recovery process<sup>3</sup>.

Although the MCBS Drug Coverage Questionnaire (RXQ) currently asks about Part D Low Income Subsidy (LIS) assistance that beneficiaries may receive, CMS currently has no way of capturing information about beneficiaries who are eligible but not enrolled in the MSP program. To address this gap, CMS is adding two items to the KNQ starting in Winter 2023 Round 95 to assess use of the MSP program. The first item provides a definition of the MSP program and asks if the beneficiary receives assistance from the program. For those who say no, a second item asks if the beneficiary applied to their state Medicare office for help with medical expenses. These items are formatted in a way similar to the RXQ items that ask about assistance for Part D expenses. Administration of the two new items is straightforward; results of a small cognitive testing effort are found in Attachment 7. Adding these items to the MCBS will help to identify general barriers to enrollment as well as ascertain characteristics of beneficiaries who are eligible but not enrolled. Further, these items will help CMS develop information campaigns and outreach for beneficiaries who could get assistance with paying for their deductibles, coinsurance, and copayments. These items will be added to the KNQ beginning in Winter 2023 Round 95 where they will be fielded annually during the Winter round; this will result in an increase of 1.4 minutes for the Winter round interview.

- **Add One Item about the Beneficiary’s Right to File a Complaint or Appeal.** This revision adds one item about beneficiaries’ knowledge about their right to file a complaint or appeal under the Medicare program to KNQ. The Beneficiary and Family Centered Care Quality Improvement Organization Program (BFCC-QIO) is a national statutorily mandated program intended to help Medicare beneficiaries exercise their right to high quality health care. Required under Sections 1152-1154 of the Social Security Act, the QIO Program is an important resource in CMS’ effort to improve quality and efficiency of care for Medicare beneficiaries. BFCC-QIOs manage all beneficiary complaints and quality of care reviews to ensure consistency in the review process. They also handle cases in which beneficiaries want to appeal a health care provider’s decision to discharge them from the hospital or discontinue other types of services<sup>4</sup>. Beneficiary experiences, whether positive or negative, give the QIO Program the perspective to identify opportunities for improvement, develop solutions that address the real needs of patients, and inspire action by health professionals<sup>5</sup>. The BFCC-QIO uses information found through review of episodes of care with the input of patients, patient representatives, and providers to identify opportunities to improve the quality of care provided and address utilization issues. Most episodes of care QIOs review are identified via complaints or appeals from Medicare beneficiaries or their families. In its review, the QIO aims to ensure that this voice is heard to improve care, not just for the beneficiary, but for all patients in similar care situations. As they do this, QIOs review the quality of care in the context of practice guidelines, the current evidence base, and the community

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<sup>3</sup> Henry J. Kaiser Family Foundation, “Medicare Advantage Fact Sheet” (Menlo Park, Calif.: Kaiser Family Foundation, March 2004).

<sup>4</sup> <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs>

<sup>5</sup> Centers for Medicare and Medicaid Services. (n.d.). About BFCC-QIOS. qioprogram. Retrieved December 1, 2021, from <https://qioprogram.org/about/what-are-qios>

standard of practice<sup>6</sup>. Given the importance of beneficiary engagement in improving how health care is delivered, it is essential that the BFCC-QIO program understands Medicare beneficiaries' awareness about their rights under the Medicare program. Complaints and appeals are vital to supporting the rights and services for Medicare beneficiaries, identifying opportunities for standardizing quality of care, and increasing patient safety.

The BFCC-QIO program routinely surveys beneficiaries who file complaints to ascertain customer satisfaction with their program. However, it is unknown what percentage of the population has not complained because they are unaware of their rights. To close this measurement gap, BFCC-QIO and CMS have collaborated on a new KNQ item that will be implemented starting in Winter 2023 Round 85. The new item will provide respondents with a brief explanation of their right to appeal or file a complaint under the Medicare program. The survey will then ask beneficiaries if they would know how to file a complaint or appeal with Medicare to address concerns about their quality of care. This item was tested with a small number of respondents and was refined based on the testing results (Attachment 7). Adding this item to the MCBS will help the BFCC-QIO program understand how well it is meeting its mandate to ensure patient's rights. It will also give CMS and BFCC NCORC a baseline understanding of beneficiary awareness that can then be tracked over time to measure whether they are successfully raising awareness. This item will be added to the KNQ beginning in Winter 2023 Round 95 where it will be fielded annually during the Winter round; this will result in an increase of 0.5 minutes for the Winter round interview.

- **Add One Item about the Use of Cannabidiol for Pain Management.** The Chronic Pain Questionnaire (CPQ) section is administered once per year in the Summer round. This revision adds one item to the CPQ about the use of cannabidiol (CBD) for pain management. The existing CPQ was designed by the National Pain Strategy (NPS), an Interagency Working Group created by the Department of Health and Human Services' Interagency Pain Research Coordinating Committee (IPRCC) to enhance pain research efforts, promote collaboration across the government, and improve pain-related treatment strategies<sup>7</sup>. According to data collected by the 2018 MCBS CPQ, approximately 78% of Medicare beneficiaries experience chronic pain. Over half (57%) of these beneficiaries say their chronic pain limits their lives or work<sup>8</sup>. Multiple comorbidities and the risk of polypharmacy make it a challenge to determine the appropriate drug, dosage, and maintenance of therapy to manage pain. Opioids are the most commonly used agents for this purpose in the elderly. However, older adults face unique health challenges that can make them more susceptible to opioid use and misuse<sup>9</sup>. A recent study on elderly patients greater than 65 years of age using cannabinoids for various conditions showed a marked reduction in pain and a better safety profile compared to opioids<sup>10</sup>. However, the safety of

<sup>6</sup> Mims, Adrienne D., Jane C. Pederson, and Jay A. Gold. "Healthcare changes and the affordable care act: a physician call to action quality improvement organizations." *Healthcare changes and the Affordable Care Act*. Springer, Cham, 2015. 13-31.

<sup>7</sup> [Interagency Pain Research Coordinating Committee](#)

<sup>8</sup> <https://www.cms.gov/files/document/mcbs-2018-survey-file-chronic-pain-infographic.pdf>

<sup>9</sup> Dean O. Prescription drug abuse among older adults. *AARP Public Policy Institute*. 2017 Aug. <https://www.aarp.org/content/dam/aarp/ppi/2017/07/prescription-drug-abuse-among-older-adults.pdf>. Accessed August 27, 2021.

<sup>10</sup> Ali, A., Arif, A. W., Bhan, C., Kumar, D., Malik, M. B., Sayyed, Z., Akhtar, K. H., & Ahmad, M. Q. (2018).

long-term therapy has not been established<sup>11</sup>. As the use of CBD across the U.S. has increased for the management of pain, measures of pain treatment modalities should include CBD.

The existing CPQ section measures the prevalence of pain in the elderly and disabled Medicare population. For beneficiaries reporting chronic pain, the section also asks about current treatment modalities, including the use of alternative medical interventions such as massage and meditation. Starting in Summer 2023 Round 96, CMS will add the use of CBD to an existing series asking about other non-medication management methods for chronic pain to understand its use. This new item performed well and was easily understood during a small cognitive testing effort (see Attachment 7). This item will be added to the CPQ beginning in Summer 2023 Round 94 where it will be fielded annually during the Summer round; this will result in an increase of 0.25 minutes for the Summer round interview.

- **Add Five Items about the Prevalence of Bowel Incontinence.** The Health Status and Functioning Questionnaire (HFQ) section is administered once per year in the Fall round. The revision adds five items to the HFQ to measure the prevalence and management of bowel incontinence. According to data from the 2007-2010 National Health and Nutrition Examination Survey (NHANES), over half of noninstitutionalized adults aged 65 and over reported some type of incontinence, including urinary leakage and/or accidental bowel leakage of mucus, liquid stool, or solid stool. About 8% of adults aged 65 and over had moderate, severe, or very severe bowel leakage<sup>12</sup>. In older adults, incontinence is associated with multiple interacting factors, including chronic conditions such as diabetes or stroke, inadequate fiber or water intake, neurologic and psychiatric conditions, cognitive impairment, and mobility impairment. Use of certain medications and polypharmacy may also contribute to bowel incontinence. Bowel incontinence has serious implications for quality of life, impacting one's emotional, physical, and economic well-being. Further, it is associated with depression, anxiety, and self-isolation. Incontinence is also a predictor of functional limitations and is associated with an increase in falls, which may result in injuries or hospitalization<sup>13</sup>.

Although common among older adults, bowel incontinence is not sufficiently discussed in health care settings. A 2018 study showed that most primary care providers screen for urinary incontinence but not bowel incontinence, despite the fact that these two issues can

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Managing Chronic Pain in the Elderly: An Overview of the Recent Therapeutic Advancements. *Cureus*, 10(9), e3293. <https://doi.org/10.7759/cureus.3293>

<sup>11</sup> Argueta DA, Ventura CM, Kiven S, Sagi V, Gupta K. A Balanced Approach for Cannabidiol Use in Chronic Pain. *Front Pharmacol*, 2020; 11: 561. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7204604/>

<sup>12</sup> Gorina Y, Schappert S, Bercovitz A, et al. Prevalence of incontinence among older Americans. *National Center for Health Statistics. Vital Health Stat* 3(36). 2014.

<sup>13</sup> Farage MA, Miller KW, Berardesca E, Maibach H. Psychosocial and societal burden of incontinence in the aged population: a review. *Archives of Gynecology and Obstetrics*, 277: 285-290 (2008). <https://link.springer.com/article/10.1007/s00404-007-0505-3>

be related<sup>14, 15</sup>. Further, a 2015 study found that less than a third of adults aged 70 and over with bowel incontinence discussed this problem with their primary care physician. Those who had mild symptoms of bowel incontinence had little to no knowledge of the treatments available to them<sup>16</sup>.

Although the MCBS collects information on urinary incontinence, not enough is known about Medicare beneficiaries with bowel incontinence. To address this measurement gap, several items were sourced from a 2004 Mayo Clinic Study<sup>17</sup> and adapted to model the urinary incontinence items in the HFQ to capture prevalence and type of stool leakage. Beneficiaries are first asked if they have experienced several types of bowel incontinence including leaking gas, leaking a small amount of stool, leaking a moderate amount of stool, and leaking a large amount of liquid stool. Beneficiaries who respond affirmatively to any type of bowel incontinence are next asked if they have talked with their health care provider about this issue. These items were refined based on the results of a small cognitive testing effort (see Attachment 7). Incorporating these items on the MCBS starting in Fall 2023 Round 97 will allow CMS to understand the prevalence of bowel incontinence among beneficiaries and develop better awareness and outreach regarding this medical issue. These items will be added to the HFQ beginning in Fall 2023 Round 97 where they will be fielded annually during the Fall round; this will result in an increase of 0.8 minutes for the Fall round interview.

- **Add Three Items about Oral Health.** This revision adds three items about oral health to the HFQ. Older adults with the poorest oral health tend to be those who are economically disadvantaged, lack insurance, and are members of racial and ethnic minorities. Being disabled, homebound, or institutionalized also increases the risk of poor oral health<sup>18</sup>. Oral health problems in older adults include untreated tooth decay, gum disease, tooth loss, oral cancer, and chronic diseases stemming from untreated inflammation in the mouth, which can be exacerbated by dry mouth – a common side effect of many medications commonly taken by those aged 65 and older<sup>19</sup>. There is also substantial evidence that periodontitis is a risk factor for certain systemic diseases, and impaired oral health, including missing teeth and dry mouth, has been associated with mastication and

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<sup>14</sup> Brown HW, Guan W, Schmul NB, Smith PD, Whitehead WE, Rogers RG. If We Don't Ask, They Won't Tell Us: Screening for Urinary and Fecal Incontinence by Primary Care Providers. 2019, 31 (5) 774-782. JABFM <https://www.jabfm.org/content/31/5/774.short>

<sup>15</sup> Whitehead WE, Borrud L, Goode PS, Meikle S, Mueller ER, Tuteja A, et al. Fecal incontinence in U.S. adults: epidemiology and risk factors. *Gastroenterology*, 2009 Aug; 137 (2): 512-7. <https://pubmed.ncbi.nlm.nih.gov/19410574/>

<sup>16</sup> Kunduru L, Min Kim S, Keymen S, Whitehead W. Factors that affect consultation and screening for fecal incontinence. *Clin Gastroenterol Hepatol*. 2015 Apr; 13 (4): 709-16. <https://pubmed.ncbi.nlm.nih.gov/25148761/>

<sup>17</sup> Bharucha AE, Locke GR 3rd, Seide BM, Zinsmeister AR. A new questionnaire for constipation and faecal incontinence. *Aliment Pharmacol Ther*. 2004 Aug 1;20(3):355-64. doi: 10.1111/j.1365-2036.2004.02028.x. PMID: 15274673

<sup>18</sup> Patel N, Fils-Aime R, Li CH, Lin M, Robison V. Prevalence of Past-Year Dental Visit Among US Adults Aged 50 Years or Older, With Selected Chronic Diseases, 2018. Centers for Disease Control and Prevention. Research Brief. Volume 18, April 29, 2021. [https://www.cdc.gov/pcd/issues/2021/20\\_0576.htm](https://www.cdc.gov/pcd/issues/2021/20_0576.htm)

<sup>19</sup> [https://www.cdc.gov/oralhealth/basics/adult-oral-health/adult\\_older.htm](https://www.cdc.gov/oralhealth/basics/adult-oral-health/adult_older.htm)

nutritional problems, especially among the elderly, with highly negative effects on their quality of life<sup>20</sup>.

Although the MCBS currently captures some oral health data, measures for dry mouth symptoms, tooth sensitivity, and overall oral health are needed to understand the impact of poor oral health on the overall health of Medicare beneficiaries. To address this gap, one item sourced from the 2019-2020 NHANES will be added to the MCBS starting in Fall 2023 Round 97 to ask about health of the beneficiary's teeth and gums<sup>21</sup>. In addition, two items adapted from the National Health Interview Survey (NHIS) 2008 Oral Health Supplement<sup>22</sup> and the World Health Organization Oral Health Survey<sup>23</sup> will be added to the HFQ starting in Fall 2023 Round 97 to assess the prevalence of dry mouth and tooth sensitivity. These items will be added to the HFQ beginning in Fall 2023 Round 97 where they will be fielded annually during the Fall round; this will result in an increase of 0.4 minutes for the Fall round interview.

- **Add Eight Health Equity Items about Perceived Discrimination from Health Care Providers.** The Satisfaction with Care Questionnaire (SCQ) is administered once per year during the Fall round. This revision adds eight items to the SCQ to improve measures of health equity, including perceived discrimination from health care providers due to certain personal attributes. Executive Order 13985<sup>24</sup>, issued in January of 2021, called upon agencies to identify and work to redress inequities in their policies and programs that create barriers to equal opportunity to ensure that everyone can reach their highest potential. Differential treatment within the medical community is an important source of inequity that can lead to differences in health outcomes and quality of care. Accordingly, following the request from the Office of Minority Health, CMS proposes to add 8 items to the SCQ starting in Fall 2023 Round 97. These items will be administered annually in the Fall round and will ask the beneficiary to identify whether they have been treated in an unfair or insensitive way by their medical providers based on their race or ethnicity, language or accent, gender or gender identity, sexual orientation, age, culture or religion, disability, or medical history. This series of items was developed and will be undergoing testing for implementation on Medicare Advantage (MA) and Prescription Drug Plan (PDP) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Web Mode Field Test (pending OMB approval. This series performed well during a small cognitive testing effort conducted by CMS (see Attachment 7). Adding this series to the MCBS represents the best opportunity to align MCBS data collection with EO 13985. These data will allow CMS to capture the most actionable and impactful information about health care experiences that directly influence health outcomes and will provide CMS with additional measures for assessing health equity and fair treatment for underserved populations. These items will be added to the SCQ beginning in Fall 2023

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<sup>20</sup> Gil-Montoya, J. A., de Mello, A. L., Barrios, R., Gonzalez-Moles, M. A., & Bravo, M. (2015). Oral health in the elderly patient and its impact on general well-being: a nonsystematic review. *Clinical interventions in aging*, 10, 461–467. <https://doi.org/10.2147/CIA.S54630>

<sup>21</sup> [https://www.cdc.gov/nchs/data/nhanes/2019-2020/questionnaires/OHQ\\_K.pdf](https://www.cdc.gov/nchs/data/nhanes/2019-2020/questionnaires/OHQ_K.pdf)

<sup>22</sup> [https://ftp.cdc.gov/pub/health\\_statistics/nchs/Dataset\\_Documentation/NHIS/2008/srvydesc.pdf](https://ftp.cdc.gov/pub/health_statistics/nchs/Dataset_Documentation/NHIS/2008/srvydesc.pdf)

<sup>23</sup> <https://www.who.int/publications/i/item/9789241548649>

<sup>24</sup> <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>

Round 97 where they will be fielded annually during the Fall round; this will result in an increase of 0.9 minutes for the Fall round interview.

- **Add Two Socio-Demographic Items about Religious Affiliation to Improve Measures of Health Equity.** The Demographics and Income Questionnaire (DIQ) is administered annually during the Fall round. This section collects important socio-demographic information that is not available in administrative records and that can be used in analysis to identify issues of inequity for health care access and use. One of the few sociodemographic items not currently collected by the survey includes religious affiliation. To further support alignment with Executive Order 13985, two items from the 2020 General Social Survey will be added to the DIQ to ask for the beneficiary’s religious affiliation starting in Fall 2023 Round 97<sup>25</sup>. Adding two items to the DIQ about religious affiliation will expand the ability of analysts to assess differences in health care access and outcomes related to health equity. Further, these new items enhance information collected in the eight new health equity items proposed for addition to the SCQ. Collecting religious affiliation in DIQ will allow analysts to compare SCQ responses for beneficiaries who report perceived discrimination from health care providers because of their culture or religion. These items will be added to the DIQ beginning in Fall 2023 Round 97 where they will be fielded annually during the Fall round; this will result in an increase of 0.3 minutes for the Fall round interview.
- **Add Four Socio-Demographic Items about Sexual Orientation and Gender Identity to Improve Measures of Health Equity.** Another important gap in sociodemographic information on the MCBS survey includes a lack of items collecting sexual orientation and gender identity. Adding sexual orientation and gender identity items to the survey is part of CMS’ strategy to inform “Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity and Sexual Orientation”. Issued in January 2021<sup>26</sup>, this Executive Order called upon agencies to identify existing and new policies to promote equal treatment under the law and ensure that all persons are able to access healthcare and other essential services without being subjected to sex discrimination. To support alignment with Executive Order 13988, two items from the NHIS<sup>27</sup> will be added to the MCBS to collect sexual orientation. The first item will ask the beneficiary if they think of themselves as gay/lesbian, straight, bisexual, or something else. If the beneficiary responds “something else”, they will be asked for a verbatim response. Verbatim responses will be reviewed and back-coded to monitor changes in preferred terminology over time and to assess the potential for future inclusion of new response options. These items were previously cognitively tested under MCBS Generic Clearance (OMB No. 0938-1275) and performed well (see summary report in Attachment 8). The items have been fielded on the NHIS since 2013, where they have been closely monitored for comprehension and sensitivity<sup>28</sup>. The proposed items also align with recommendations from the National Academies of Sciences, Engineering, and

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<sup>25</sup> [http://gss.norc.org/Documents/quex/GSS2020panel\\_Ballot1\\_English\\_CAPI.pdf](http://gss.norc.org/Documents/quex/GSS2020panel_Ballot1_English_CAPI.pdf)

<sup>26</sup> <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-preventing-and-combating-discrimination-on-basis-of-gender-identity-or-sexual-orientation/>

<sup>27</sup> [https://ftp.cdc.gov/pub/Health\\_Statistics/NCHS/Survey\\_Questionnaires/NHIS/2022/EnglishQuest-508.pdf](https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Survey_Questionnaires/NHIS/2022/EnglishQuest-508.pdf)

<sup>28</sup> [https://www.cdc.gov/nchs/nhis/sexual\\_orientation/questionnaire.htm](https://www.cdc.gov/nchs/nhis/sexual_orientation/questionnaire.htm)



Medicine’s (NASEM’s) recent report, “Measuring Sex, Gender Identity, and Sexual Orientation”<sup>29</sup>.

Two items about gender identity will also be included from the U.S. Census Bureau’s Household Pulse Survey<sup>30</sup>. This series uses a two-step approach. Beneficiaries are first asked to report their sex assigned at birth on their original birth certificate (male or female). Next, respondents are asked to report their current gender identity (male, female, transgender, none of these). This same two-step series is supported by the NASEM report on measuring gender identity and is also being evaluated in the 2022 NHIS as part of an experiment that varies the order of items about sex assigned at birth and gender identity and varies between two options for wording the gender identity question<sup>31</sup>. This experiment will enable NCHS to understand whether question order or the wording of the gender identity question affects the level of consistency between these items and will inform long-term efforts to include gender identity questions on the NHIS. As the results of this experiment become available, CMS will collaborate with NCHS to align comparable MCBS items. Including sexual orientation and gender identity questions on the MCBS will provide nationally representative data on topics such as the accessibility and utilization of health care services by the Lesbian, Gay, Bisexual, and Transgender (LGBT) populations and the resulting health disparities that impact this community. These items will be added to the DIQ in Fall 2023 Round 97 where they will be fielded annually during the Fall round; this will result in an increase of 0.5 minutes for the Fall round interview.

Changes that will **decrease** respondent burden include:

- **Discontinue the Standalone COVID-19 Community Supplement.** The current clearance provides approval to administer COVID-19 items each round via a standalone Supplement or as part of the main MCBS questionnaires. The Supplement contains about 150 items and takes about 15 minutes to administer each round, for a total annual burden of 45 minutes. Starting in 2023, the MCBS COVID-19 Community Supplement will be discontinued resulting in a deletion of about 114 items. About 36 COVID-19 items that are expected to provide critical information in 2023 and beyond will be retained and integrated into the main MCBS Community questionnaire. The retained items will be administered via two streamlined sections:
  - The COVID-19 Questionnaire (CVQ) will be administered each round and will ask whether beneficiaries have had a COVID-19 test, diagnosis, or vaccination since the last interview. While this section has about 30 total questions, only 7 items will be asked of all respondents each round; based on skip logic, the remaining 23 retained items are only asked to a small number of respondents as a follow on to a previous question. For example:

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<sup>29</sup> National Academies of Sciences, Engineering, and Medicine 2022. *Measuring Sex, Gender Identity, and Sexual Orientation*. Washington, D.C: The National Academies Press. <https://doi.org/10.17226/26424>.

<sup>30</sup> <https://www.census.gov/library/stories/2021/08/household-pulse-survey-updates-sex-question-now-asks-sexual-orientation-and-gender-identity.html>

<sup>31</sup> <https://omb.report/icr/202102-0920-005>

- Beneficiaries who report having a COVID-19 test during the reference period will receive follow-up questions about the test results, out of pocket payment, and wait time for test results.
- Beneficiaries with a positive COVID-19 diagnosis during the reference period will also be asked whether they sought medical care for their COVID-19 illness and if not, the reason(s) why not.
- Beneficiaries who received a new COVID-19 vaccination dose since the last interview will be asked for details about the month and year of vaccination, vaccine manufacturer, and location of vaccination.
- Beneficiaries who did not receive a new COVID-19 vaccination dose since the last interview will be asked for their reason why not (e.g., not eligible for an additional dose at this time, fears about the vaccine, etc.).

Based on the results of timings tests, the streamlined CVQ is expected to take approximately two minutes to administer each round on average.

- In addition, six items about the availability and use of telemedicine, previously administered as part of the standalone COVID-19 Supplement, will now be administered in a Telemedicine Questionnaire (TLQ) within the main Community questionnaire. These items will be administered once per year in the Winter round and will take about 1 minute to administer.
- **Discontinue the Standalone COVID-19 Facility Supplement.** The current clearance provides approval to administer Facility-related COVID-19 items each round via a standalone Supplement or as part of the main MCBS questionnaires. The Supplement contains about 90 items and takes about 15 minutes to administer each round, for a total annual burden of 45 minutes. Starting in 2023, the MCBS COVID-19 Facility Supplement will be discontinued resulting in a deletion of about 50 items. About 40 COVID-19 items that are expected to provide critical information in 2023 and beyond will be retained and fielded as part of the main MCBS Facility instrument. The retained items will be administered via two streamlined sections:
  - The Beneficiary-Level COVID-19 (CV) Questionnaire will be administered each round and will ask whether beneficiaries have had a COVID-19 test, diagnosis, or vaccination since the last interview. Similar to the COVID-19 Questionnaire (CVQ) in the Community questionnaire, follow-up details will be asked for beneficiaries who have received a test, positive diagnosis, or new COVID-19 vaccination dose. Only 3 items in this section will be asked of all respondents; the remaining 13 items are only asked to a small number of respondents as a follow on to previous questions. This section will take approximately two minutes to administer each round.
  - The Facility-Level COVID-19 (FC) Questionnaire will be administered once per year in the Fall round and will ask about the availability of telemedicine services inside and outside of the facility, facility measures to prevent and control the spread of COVID-19, and changes in mental health services due to the pandemic. Approximately 9 items will be administered during most interviews; the remaining 15 items will be asked to a small number of respondents as a follow on

to previous questions. This section will take approximately three minutes to administer in the Fall round only.

Changes that will **have no impact to** respondent burden include:

- Add New Respondent Materials.** To maximize outreach CMS is requesting approval to add several new respondent materials, including letters and frequently asked questions. These new materials are designed to increase understanding of the survey and thus improve participation. These recommendations are based on feedback gathered from current field interviewers about the questions that beneficiaries most frequently ask about the survey, as well as materials to address questions raised by Facility staff members. Furthermore, with the shift to incorporate more phone data collection since the onset of the COVID-19 pandemic, several new letters focus on encouraging participation with new panel members (i.e., Baseline panel). Attachment 9 contains a table that lists these new materials and their intended purpose. These new letters have no change to respondent burden. Selecting from a group of letters that contain targeted wording to improve response will provide additional flexibility for interviewers, especially in situations that require refusal conversion.

Table A-2 summarizes the new content requested to be added to the Community instrument and their associated effect on burden (minutes).

**Table A-2: Increased Burden Associated with New Content Revisions to the Community Instrument**

Community Additions	Section	Winter 2023 Round 95	Summer 2023 Round 96	Fall 2023 Round 97	Total Annual Increase
Use of MSP Program	KNQ	1.4	-	-	1.4 minutes
Right to File a Complaint or Appeal	KNQ	0.5	-	-	0.5 minutes
Use of CBD	CPQ	-	0.25	-	0.25 minutes
Bowel Incontinence	HFQ	-	-	0.8	0.8 minutes
Oral Health	HFQ	-	-	0.7	0.7 minutes
Health Equity— Perceived Discrimination from Health Care Providers	SCQ	-	-	0.9	0.9 minutes
Health Equity— Religious Affiliation	DIQ	-	-	0.3	0.3 minutes
Health Equity—Sexual Orientation and Gender Identity	DIQ	-	-	0.5	0.5 minutes
<b>Total Minutes Added</b>		<b>1.9 minutes</b>	<b>0.25 minutes</b>	<b>3.2 minutes</b>	<b>5.4 minutes</b>
<b>Net Annual Effect Increase in Community</b>					<b>5.4 minutes</b>

<b>Community Additions</b>	<b>Section</b>	<b>Winter 2023 Round 95</b>	<b>Summer 2023 Round 96</b>	<b>Fall 2023 Round 97</b>	<b>Total Annual Increase</b>
<b>Burden</b>					

Table A-3 summarizes the decrease in burden associated with discontinuing the standalone COVID-19 Community and Facility Supplements and retaining only a subset of critical items within the main Community and Facility instruments.

**Table A-3: Decreased Burden Associated with Discontinuing Standalone COVID-19 Supplements**

<b>Community</b>	<b>Section</b>	<b>Winter 2023 Round 95</b>	<b>Summer 2023 Round 96</b>	<b>Fall 2023 Round 97</b>	<b>Total Annual Decrease</b>
Items Retained via COVID-19 Questionnaire	CVQ	2	2	2	6 minutes
Items Retained via Telemedicine Questionnaire	TLQ	1	0	0	1 minute
Items Removed by Discontinuing COVID-19 Supplement	Standalone	12	13	13	38 minutes
<b>Total Items in Original COVID-19 Supplement</b>	<b>Standalone</b>	<b>15</b>	<b>15</b>	<b>15</b>	<b>45 minutes</b>
<b>Net Annual Effect Decrease in Community Burden</b>					<b>38 minutes</b>

<b>Facility</b>	<b>Section</b>	<b>Winter 2023 Round 95</b>	<b>Summer 2023 Round 96</b>	<b>Fall 2023 Round 97</b>	<b>Total Annual Decrease</b>
Items Retained via Beneficiary-Level COVID-19 Questionnaire	CV	2	2	2	6 minutes
Items Retained via Facility-Level COVID-19 Questionnaire	FC	0	0	3	3 minutes
Items Removed by Discontinuing COVID-19 Supplement	Standalone	13	13	10	36 minutes
<b>Total Items in</b>	<b>Standalone</b>	<b>15</b>	<b>15</b>	<b>15</b>	<b>45 minutes</b>

Facility	Section	Winter 2023 Round 95	Summer 2023 Round 96	Fall 2023 Round 97	Total Annual Decrease
<b>Original COVID-19 Supplement</b>					
<b>Net Annual Effect Decrease in Facility Burden</b>		<b>13</b>	<b>13</b>	<b>10</b>	<b>36 minutes</b>

### **A3. Use of Information Technology and Burden Reduction**

The MCBS takes full advantage of advances in survey methodology by administering the survey electronically. Whether by phone or in-person, the MCBS is administered by trained field interviewers using computer-assisted personal interviewing (CAPI), which functions with programmed edit checks, reduces respondent burden by minimizing the potential for double reporting and inconsistent responses. CAPI enables the interviewer to move through complex skip patterns quickly, which reduces respondent burden by shortening the interview and eliminating the need for call backs to correct errors. CAPI also greatly increases the efficiency of the interview in the following ways:

- a. CAPI tailors the sequence of questions to the responses of the interviewee, resulting in few – if any – interviewer skip errors. The natural flow of the interview is maintained even when the pattern of questions is complex.
- b. CAPI automatically provides “fills”, or word choices within questions. For example, once respondent gender is recorded, the instrument automatically inserts pronouns such as “you”, “he”, or “she”, as appropriate, for the duration of the interview. The sample person’s name, date of the last interview, and other items can also be filled as needed.
- c. CAPI maintains rosters or lists created during the interview, such as household members, health insurance plans, medical conditions, providers, visit dates, prescription drugs, and people who help with daily activities. These rosters can be used to structure questions, e.g., cycling through a series of doctor visits and checking for missing information. Interviewers can select items from a roster, add items, or correct them. Rosters are carried over from one interview to the next.
- d. CAPI displays questions with identical question stems and response options in a grid-style format instead of displaying each question on separate screens.
- e. CAPI edits entries for range and consistency. The interviewer can make corrections immediately. Information missing from a previous round can be inserted in the questionnaire.
- f. CAPI allows instantaneous calculations to be made, such as the amount remaining to be paid on a medical bill after totaling several payments.
- g. CAPI allows for the instrument to be pre-loaded with responses recorded from previous data collection rounds and from administrative records to reduce respondent burden and provide for more accurate reporting of subsequent responses.

- h. Interviewers use the computer to electronically transmit completed cases to the central office, and the central office uses automated management processes to balance interviewer caseload in order to provide for data collection efficiency in the field.

MCBS data collection also takes advantage of sophisticated technologies for efficient sampling as well as data editing and processing. Additionally, locating of respondents utilizes available technologies that have reduced on-the-ground searches.

#### ***A4. Efforts to Identify Duplication and Use of Similar Information***

This information collection is unique and does not duplicate any other effort and the same information cannot be obtained from any other source. This is especially true due to the unique panel design which follows respondents over a four-year period both in the community as well as in long term care facilities. This design enables CMS to capture more complete data associated with costs and utilization of health care.

During the development and initial administration of the MCBS, a number of people inside and outside the Federal government were consulted. This consultation included issues of design, content, and statistical methodology and analysis. This effort was reexamined in 2013 using an independent contractor. In both instances, none of the people contacted were aware of duplicative information, nor were they aware of any other survey that duplicates the efforts of MCBS.

Further, in 2015-2016, the Department of Health and Human Services (DHHS) underwent an intensive review of health surveys to align like questions, reduce duplication, and ensure that official estimates were being provided by the appropriate survey<sup>32</sup>. The DHHS review determined that data collected by the MCBS are unique even though similar topics are asked by the National Health Interview Survey (NHIS), the National Health and Nutrition Examination Survey (NHANES), and other federal surveys. Although NHIS, for example, asks similar questions about health insurance coverage, the usage of MCBS data is different, particularly given the ability to link MCBS survey data to Medicare administrative data and cost related data. Unlike other federal surveys, CMS uses health insurance information collected by the MCBS to determine the cost burden of premiums paid by beneficiaries as well as to determine the cost of additional supplemental plans paid for the Medicare covered and non-covered medical expenses. Using the MCBS, CMS examines the cost of reported medical events, and determines with Medicare administrative data and cost information collected from the beneficiary what the true out of pocket costs are to the beneficiary. CMS also uses the information to see whether private plans such as employer provided plans are paying for the Medicare premiums for Part D and/or Part C for currently employed beneficiaries as well as retired beneficiaries.

In addition, CMS has undertaken exhaustive reviews of the literature and other data sources. In no instance have we identified another source of data that would be an effective substitute for the MCBS.

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<sup>32</sup> HHS Data Council Co-Chairs memorandum to the Secretary of the Department of Health and Human Services, May 11, 2016

**A5. *Impact on Small Businesses and Other Small Entities***

Most of the data collected for the MCBS will be from individuals in households. However, in any given round, approximately 800 to 1,100 sample persons will reside in government-sponsored, non-profit, and for-profit institutions such as nursing and personal care homes. Some of these institutions likely qualify as small businesses. For data collected on sample persons in these institutions, their employees serve as proxies for each sample person in their care.

Interviewers who collect data on beneficiaries living in facilities make every effort to determine, for each type of question, which staff members are most able to answer them. The data collection procedures are designed to minimize the burden on facility staff by utilizing as much administrative data as possible to streamline the data collection process.

**A6. *Consequences of Collecting the Information Less Frequently***

As part of the currently approved clearance, CMS revised the longitudinal design in 2018 by reducing the number of rounds respondents participate in from 12 interviews to 11 interviews. Analysis of data collected in the 12<sup>th</sup> interview revealed that this ‘exit’ interview did not provide essential cost and use information and therefore, was eliminated.

By re-interviewing the same respondents a total of 11 times during a four-year period, the MCBS supports longitudinal as well as cross-sectional analyses. Longitudinal data provide the basis for models that analyze quantitative change over time. Policy changes can only be effectively understood by modeling the consequences of those changes on the same individuals over time. For example, the MCBS data allow us to understand how changes in copays or coverage affect the type of physicians a beneficiary may choose or the type of services a beneficiary seeks. Additionally, three interviews a year that collect full cost and event data allow CMS to assess rapid individual changes in health and wellbeing in an elderly population.

In the first round of interviewing in the MCBS, the respondent is provided with a calendar and asked to record all visits to health care providers and health care expenditures; they are also asked to retain all statements including private insurance documents, prescription drug documents and Medicare statements/bills. After the initial Baseline interview, the recall period for the MCBS is since the time of the last interview (usually not greater than four months).

In addition, the MCBS administers some sections only once a year which allows for important information to be collected, but reduces respondent burden by collecting the information less frequently.

**A7. *Special Circumstances Relating to Guidelines of 5 CFR 1320.5***

None of the special circumstances listed by OMB apply to the MCBS.

**A8. *Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies***

The 60-day Federal Register notice was published on January 21, 2022 (87 FR 3301). Three comments were received. The first comment requested that CMS share survey results at the aggregate level for Medicare Advantage (MA) and Part D beneficiaries to enable health plans to further improve person-centered outcomes. Key estimates for beneficiaries participating in MA

programs are publicly available via the MCBS Chart Book. With a Data Use Agreement, researchers can also access more detailed data for analysis. CMS will reach out to the commenter to understand the level of detail they are looking for and to answer any questions about data access. The second comment requested that CMS add measures of sexual orientation and gender identity to the demographics section of the survey. Recently, CMS determined that adding sexual orientation and gender identity is needed on the MCBS to improve measures of health equity. Therefore, this request for OMB approval of a revision to the MCBS proposes to add sexual orientation and gender identity items currently fielded on the National Health Interview Survey (NHIS) and the U.S. Census Bureau’s Household Pulse Survey to the DIQ. The third commentator asked for more information about how the survey data will be used and whether data collected can be used to retaliate against those who participate. Respondent materials included in Attachment 1 include advance letters, brochures, frequently asked questions, and outreach materials used when first gaining cooperation with respondents. These materials—as well as the MCBS website found at [mcbs.norc.org](http://mcbs.norc.org)—state that participation is voluntary and that Medicare benefits will not be affected in any way based on a decision to participate or not. Survey responses are aggregated and used for research and statistical purposes to help inform policy decisions.

CMS also regularly solicits input on questionnaire content from a large listserv as well as notification of opportunities to comment on the website ([CMS.gov/MCBS](https://www.cms.gov/MCBS) and [Research Statistics Data and Systems MCBS](#)). Also, CMS participates in interagency working groups as well as research conferences to consult with a wide variety of data users and policy officials interested in MCBS data. The 30-day Federal Register notice was published on April 4, 2022 (87 FR 19517).

#### ***A9. Explanation of Any Payment or Gift to Respondents***

The MCBS does not provide payments or gifts as incentives to respond. The most important incentive we use is to persuade the respondent that his or her participation is a service to the future of Medicare. Respondents are provided with a calendar to record all health events and provider visits for easy reference during future interviews.

#### ***A10. Assurances of Confidentiality Provided to Respondents***

On February 14, 2018, CMS published in the Federal Register a notice of a modified or altered System of Record (SOR) (System No. 09-70-0519). The notice was published in 83 Federal Register 6591.

The Community Advance Letter (Attachment 1) mailed to the respondent for in person and telephone interviewing includes the following statement regarding confidentiality of data:

“...your information will be kept private to the extent permitted by law, as prescribed by the Federal Privacy Act of 1974.”

The Community brochure (Attachment 1), which is mailed to all newly added sample members each Fall round, contains the following on respondent rights and privacy:

“The information you provide will be kept private to the extent permitted by law, as prescribed by the Privacy Act of 1974. The information you give will only be used for research and statistical purposes.”



The At the Door Sheet (Attachment 1) provided during in person interviews to the Community respondent at the door and the facility administrator and proxy respondents contains a statement of privacy protection consistent with the Privacy Act of 1974. In fielding the Community questionnaire Income and Assets module, an additional handout (Attachment 1) is provided explaining its purpose and restating the Privacy Act.

Interviewer training stresses the importance of maintaining confidentiality and project protocols are documented within the Field Interviewer manual. Field outreach and contacting procedures have been established to maintain and ensure confidentiality. These include the utilization of standard computer security procedures (dual authentication password protection for each interviewer laptop) and prohibitions on submitting personally identifiable information through electronic mail submission.

The Facility Advance Letter (Attachment 5), sent to any new facility participating in the MCBS via in person or telephone interviews, includes the following statement:

“No residents of your facility will be contacted directly. All of the information your organization provides will be kept private to the extent permitted by law, as prescribed by The Federal Privacy Act of 1974. Your participation is voluntary, and your relationship with programs administered by CMS will not be affected in any way by whether or not you participate.”

Participating facilities also receive a HIPAA Letter (Attachment 5), which includes the following regarding the Health Insurance Portability and Accountability Act (HIPAA) regulations:

“I am writing to address any concerns you may have about your facility’s participation in the Medicare Current Beneficiary Survey (MCBS) as it relates to the Health Insurance Portability and Accountability Act (HIPAA) regulations. Please be assured that the standards of privacy of protected individually identifiable health information implemented under the HIPAA privacy regulation do not affect the data being collected for MCBS. Specifically, your cooperation with the MCBS will not violate the HIPAA privacy regulations. Nor will it require any additional privacy disclosure record keeping.

Under the HIPAA regulations, your facility does not need an individual’s authorization to disclose their protected health information to a health plan, such as the Medicare program, when the information is being disclosed for receiving organization’s health care operations activities. This holds if both your facility and the Medicare program has or had a relationship with the individual whose protected health information is being requested, and the protected information pertains to such relationship. See 45 CFR § 164.506(c) (4).

Furthermore, participating in the MCBS will not impose additional disclosure record keeping burdens on your facility. Disclosures under 45 CFR § are explicitly exempt from the HIPAA disclosure accounting provisions. See 45 CFR § 164.528 (a) (1) (i).”

The Resident Consent Form (Attachment 5) contains the following statement:

“The information collected for MCBS will be protected by NORC at the University of Chicago, the contractor collecting the data, and by CMS. It will be used only for the purposes stated for this study. Identifiable information will not be disclosed or released to

anyone except those involved in research without the consent of the individual or the establishment except as required under the Privacy Act of 1974 (Public Law 93-579).”

Any data published will exclude information that might lead to the identification of specific individuals (e.g., ID number, claim numbers, and location codes). CMS will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to the individual privacy or other personal or property rights of the individual.

All MCBS survey staff directly involved in MCBS data collection and/or analysis activities are required to sign a Non-Disclosure Agreement as well as a NORC confidentiality agreement.

#### ***A11. Justification for Sensitive Questions***

In general, the MCBS does not ask sensitive questions. However, for a small number of respondents, there may be some questionnaire items that are considered to be sensitive. All interviewers are trained on how to handle respondent concerns about questions being sensitive.

For example, some respondents might view questions on the Demographics and Income Questionnaire (DIQ) to be sensitive, such as items about race, ethnicity, sexual orientation, gender identity, and income and assets. Despite the potentially sensitive nature of these items, years of data collection on these topics on the MCBS, NHIS, and other Federal surveys indicates that respondents are willing to respond and do not report sensitivity concerns to interviewers.

The Community instrument asks for respondents’ perception of their health care, including any issues they may have experienced with their health care providers. These items may be considered sensitive for some respondents, depending on their health care experiences. It also includes some questions about activities of daily living, such as whether the respondent needs help bathing. Some respondents view these kinds of questions in a sensitive manner. In addition, there are a few questions that ask about alcohol use, obesity screening, mental health screening, and HIV testing that some respondents might perceive as sensitive.

#### ***A12. Estimates of Annualized Burden Hours and Costs***

Table B-12a shows the estimates of the annual respondent burden, based on the projected number of completed interviews per round and the estimated length of each interview (including the net additions and deletions requested in this clearance). On average, the annual burden for the MCBS is based on three interviews per respondent. The number of respondents changes every round and every year and in part, depends on the response rate (both initially and through the life of their participation over 11 rounds of data collection). In addition to being a longitudinal panel survey, the MCBS design calls for one panel to be retired during each Winter round, and a new panel selected to replace it each Fall round. Response rates per round and annually are carefully monitored and reviewed to determine the size of the next Incoming Panel. The size of the new panel is designed to provide a stable number of respondents across all panels participating in the survey annually and this size changes annually depending on prior year response rates and the number of active participants still engaged in the survey. **In January 2023, we estimate that our annual burden will be 46,680 hours for the survey, 7,746 hours less than the estimate in the current clearance. The reduction is largely due to the elimination of the standalone COVID-19 supplement that is included in the current OMB clearance.**

**Table B-12: Estimates of the Annual Respondent Burden in 2023**

<b>Community Rounds 95-97</b>	<b>Time per Response</b>	<b>Number of Interviews</b>	<b>Expected Number of Completed Interviews Per Round</b>	<b>Burden Hours</b>
Winter 2023 Round 95 Continuing Interview	72 minutes	1	11,071	13,341
Summer 2023 Round 96 Continuing Interview	82 minutes	1	8,020	10,914
Fall 2023 Round 97 Baseline Interview	83.5 minutes	1	5,749	8,010
Fall 2023 Round 97 Continuing Interview	105.5 minutes	1	6,888	12,088
<b>Field Manager follow-up with 5% of Completed Interviews</b>	5 minutes	-	1,586	132

<b>Facility Rounds 95-97</b>	<b>Time per Response</b>	<b>Number of Interviews</b>	<b>Expected Number of Completed Interviews Per Round</b>	<b>Burden Hours</b>
Winter 2023 Round 95 Continuing Interview	45 minutes	1	951	713
Summer 2023 Round 96 Continuing Interview	45 minutes	1	714	536
Fall 2023 Round 97 Baseline Interview	65 minutes	1	202	218
Fall 2031 Round 97 Continuing Interview	63 minutes	1	409	431
Fall 2023 Round 97 Baseline Interview for Cases with Admin Data	35 minutes	1	135	78
Fall 2023 Round 97 Continuing Interview for Cases with Admin Data	48 minutes	1	273	219
<b>Total Expected Number of Completed Interviews Annually</b>			<b>35,998</b>	
<b>Total Annual Burden Hours</b>				<b>46,680</b>
<b>Total Estimated Burden Hours – Rounds 95-103 (3 Years)</b>				<b>140,040</b>

Below provides a summary of the annual burden change from the current clearance, reflecting the increased burden of adding the seven new sets of items and the decreased burden of removing the standalone COVID-19 supplement from the Community and Facility instruments and retaining a small number of COVID-19 items.

Total annual burden hours – current clearance	54,426
Total annual burden hours – revised clearance	46,680

Total annual burden hours – difference	(7,746)
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In order to provide an estimate of the cost of participating in this survey, we must select an hourly rate to use which is then multiplied by the burden hours of the respondent. We selected the U.S. minimum wage (\$7.25 for 2022<sup>33</sup>) and multiplied it to the Total Annual Hours for Rounds 95-97 (46,680), for a Total Annual Cost Burden in terms of dollars of roughly \$338,430.00.

**A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers**

All costs associated with this effort are reported in Items 12 and 14.

**A14. Annualized Costs to the Federal Government**

The estimated cost to the government for collecting these data includes the NORC data collection contract, and direct CMS expenses for labor and travel.

The estimated cost for the annual planning, sampling, data collection and analysis for the MCBS is below.

Base Year (May 1, 2021-April 30, 2022): Survey development, operations, processing and analysis: \$20,880,830.78<sup>34</sup>

These costs include all labor hours, materials and supplies, reproduction, postage, telephone charges and indirect costs.

CMS personnel involved in MCBS include approximately 12 FTEs broken out by pay grade in Table B-14.

**Table B-14: CMS Personnel**

Grade	FTE	2022 Annual Salary	Cost to Government <sup>35</sup>
GS13 step 6	6.0	\$124,626	\$747,756
GS14 step 5	3.0	\$143,064	\$429,192
GS15 step 5	1.0	\$168,282	\$168,282
			\$1,345,230

CMS staff costs are approximately \$1,345,230. In addition, staff travel is budgeted for \$8,000. The MCBS releases its documentation as downloadable files on its public website and also on CD Rom thus eliminating its printing budget. Thus, in-house CMS cost will be \$1,353,230.

**A15. Explanation for Burden Changes (Program Adjustments)**

While this revision includes the addition of 26 questions that result in a burden increase of 5.4 minutes, reducing a large amount of COVID-19 content will offset this small increase as there

<sup>33</sup> <https://www.dol.gov/general/topic/wages/minimumwage>

<sup>34</sup> Future awards are based on execution of option years and funding availability.

<sup>35</sup> <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB.pdf>

will be a reduction of 38 minutes for the Community questionnaire and 36 minutes for the Facility instrument. Specifically, as noted earlier, the following changes are requested:

Changes that will **increase** respondent burden:

- 1.9 minutes of burden will be added to each Winter interview beginning in Winter 2023 due to the addition of three new items in the KNQ, two on the use of the MSP program and one about the beneficiary's knowledge about their right to file a complaint or appeal under the Medicare program.
- 0.25 minutes of burden will be added each Summer round starting in Summer 2023 due to the addition of one item about the use of CBD for pain management.
- 2.7 minutes of burden will be added each Fall round starting in Fall 2023 due to the addition of five items related to bowel incontinence, three items related to oral health, eight items related to health equity (perceived discrimination by health care providers), two items related to religious affiliation, and four items measuring sexual orientation and gender identity.

Changes that will **decrease** respondent burden:

- Deletion of 114 COVID-19-related items will **remove 38 minutes from the Community instrument annually** (13 minutes each Summer and Fall round and 12 minutes in the Winter round). About 36 COVID-19 items that are expected to provide critical information in 2023 and beyond will be retained and integrated into the main MCBS Community questionnaire. The retained items will be administered via two streamlined sections:
  - Retain items and 23 follow-up items (depending on skip logic) about COVID-19 testing, diagnosis and vaccination in the COVID-19 Questionnaire (CVQ) in the main MCBS Community questionnaire. Based on the results of timings tests, the streamlined CVQ is expected to take approximately two minutes to administer each round on average.
  - Retain six telemedicine items in the Telemedicine Questionnaire (TLQ) in the main MCBS Community questionnaire. These items will be administered once per year in the Winter round and will take about one minute to administer.
- Deletion of 50 COVID-19-related items from the Facility instrument will also remove **36 minutes from Facility data collection annually** (13 minutes in the Winter and Summer rounds and 10 minutes in the Fall round). About 40 COVID-19 items that are expected to provide critical information in 2023 and beyond will be retained and fielded as part of the main MCBS Facility instrument. The retained items will be administered via two streamlined sections:
  - Retain nine primary items and 15 follow-up items about telemedicine services, facility measures to prevent and control the spread of COVID-19, and changes in mental health services due to the pandemic in the Facility-Level COVID-19 (FC) Questionnaire in the main Facility instrument. This section will take approximately three minutes to administer in the Fall round only.

- o Retain three primary items and 13 follow-up items about COVID-19 testing, diagnosis, and vaccination in the Beneficiary-Level COVID-19 (CV) Questionnaire in the main Facility instrument. This section will take approximately two minutes to administer each round.

**Net impact** to respondent burden:

- As a result, the total burden has decreased to 46,575 from the previously approved total burden of 54,426. This is a net decrease of 7,851 burden hours annually.

**A16. Plans for Tabulation and Publication and Project Time Schedule**

Data files will continue to be prepared over the course of the survey. This clearance request covers data collection beginning in Round 95 (Winter 2023) through Round 103 (Fall 2025). See Table B-16a for data collection rounds and plans for data dissemination.

**Table B-16a: Annual schedule for information collection and dissemination, July 2021 - October 2027**

**Data collection schedule**

01/11/2023	Data collection starts for Winter 2023 Round 95
05/03/2023	Data collection starts for Summer 2023 Round 96
07/24/2023	Data collection starts for Fall 2023 Round 97
01/10/2024	Data collection starts for Winter 2024 Round 98
05/10/2024	Data collection starts for Summer 2024 Round 99
07/22/2024	Data collection starts for Fall 2024 Round 100
01/08/2025	Data collection starts for Winter 2025 Round 101
05/08/2025	Data collection starts for Summer 2025 Round 102
07/21/2025	Data collection starts for Fall 2025 Round 103

**Data dissemination schedule**

07/15/2022	Limited Data Set available for 2020 Survey File.
10/15/2022	Limited Data Set available for 2020 Cost Supplement File.
10/15/2022	Microdata Public Use File for 2020 data.
07/15/2023	Limited Data Set available for 2021 Survey File.
10/15/2023	Limited Data Set available for 2021 Cost Supplement File.
10/15/2023	Microdata Public Use File for 2021 data.
07/15/2024	Limited Data Set available for 2022 Survey File.
10/15/2024	Limited Data Set available for 2022 Cost Supplement File.

10/15/2024	Microdata Public Use File for 2022 data.
07/15/2025	Limited Data Set available for 2023 Survey File.
10/15/2025	Limited Data Set available for 2023 Cost Supplement File.
10/15/2025	Microdata Public Use File for 2023 data.
07/15/2026	Limited Data Set available for 2024 Survey File.
10/15/2026	Limited Data Set available for 2024 Cost Supplement File.
10/15/2026	Microdata Public Use File for 2024 data.
07/15/2027	Limited Data Set available for 2025 Survey File.
10/15/2027	Limited Data Set available for 2025 Cost Supplement File.
10/15/2027	Microdata Public Use File for 2025 data.

The Survey File contains data collected directly from respondents and supplemented by administrative items plus facility (non-cost) information and Medicare Fee-for-Service claims. The Cost Supplement File contains both individual event and summary files and can be linked to the Survey File to conduct analyses on health care cost and utilization. The Microdata Public Use File (PUF) includes data related to Medicare beneficiaries' access to care, health status, other information regarding beneficiaries' knowledge of, attitudes toward, and satisfaction with their health care, as well as demographic data and information on all types of health insurance coverage. Disclosure protections have been applied to the PUF, including de-identification and other methods. CMS posts the PUF online at [CMS MCBS Public Use File](#).

An MCBS Chartbook is issued with each annual release of the data by CMS. It provides the public with a collection of charts and tables presenting estimates from both the Survey File and Cost Supplement File. The charts and tables in the Chartbook are cross-sectional and describe the Medicare population in terms of its demographic and socioeconomic characteristics, use of and expenditures on health care, perceived health and functional status, and access to and satisfaction with health care within a given year. The Chartbook is intended as a reference for persons interested in using MCBS data to analyze the health and health care of the Medicare population. CMS regularly posts the Chartbook and data tables online at [CMS MCBS Data Tables](#).

An MCBS Early Look is issued with each annual release of the Survey File Limited Data Set by CMS. It presents preliminary estimates for demographics and selected health status and functioning, access to care, and satisfaction with care measures relevant to the community-dwelling Medicare population in advance of the MCBS Survey File release. CMS posts the Early Look online at [CMS MCBS Data Briefs](#).

#### ***A17. Display of OMB Expiration Date***

The OMB expiration date is displayed on the hardcopy respondent materials, including advance mail materials. It is also displayed on the MCBS website. When conducting in person interviews, the OMB expiration date is displayed in the CAPI instrument on the first screen (introductory script and consent) and on the last screen (thank you script), as displayed in

Attachment 6. There is no hard copy questionnaire or document to display the OMB expiration date.

***A18. Exceptions to Certification for Paperwork Reduction Act Submissions***

There are no exceptions to this certification statement.