

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

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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 late 2021. MCBS data collection will continue to include both in-person and phone interviewing to reduce costs, recognizing that in-person interviewing is necessary to improve response rates among selected populations 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. Additional detail on future data collection plans is included at the end of this section.

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 11th 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 8/31/2025). 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 14 new items to the MCBS Community questionnaires beginning in 2024. The impact of the additional content is offset by deletion of content no longer relevant. The new items cover important topics including:

- One question on beneficiary use of cannabidiol (CBD) to manage pain,
- One question on Supplemental Nutrition Assistance Program (SNAP) participation,
- Two questions on Veterans Affairs (VA) health care enrollment and utilization,
- Five questions on prevalence of bowel incontinence, and
- Five questions on oral health-related quality of life.

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 total respondent burden beginning in 2024 will be reduced as a result. This revision also includes updated respondent materials intended to increase understanding of the survey and thus, improve participation.

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, MCBS data were 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 150 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. CMS also uses the MCBS to benchmark to other federal surveys, where appropriate, and uses the information to produce estimates of health care utilization, costs, and well-being for underserved populations. CMS uses lessons learned from these analyses to inform future outreach to these populations.

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, NIH Office

of Dietary Supplements, 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), public use file (PUF) versions and accompanying documentation are 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 2024, 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 and deletions of COVID-19-specific content from the Community and Facility instruments. Updated 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 3.27 minutes** to the Community questionnaire each year starting in 2024, streamlining of COVID-19 content will **remove 4.5 minutes from the Community instrument annually** (two minutes each Summer and Fall round and 0.5 minutes in the Winter round). Deleting COVID-19 content from the Facility instrument will also remove **8.66 minutes from Facility data collection annually** (1.66 minutes in the Winter round, two minutes in the Summer round, and five minutes in the Fall round). In Section A12, we also describe efforts to use more up-to-date data collection actuals to estimate the projection of interview completes and survey length. Using updated actuals based on the most recent data – the 2022 data collection year—have resulted in a further reduction in respondent burden when compared to the current clearance estimates.

The current OMB clearance projects an annual respondent burden of 46,513 hours. This revision to the clearance reduces the annual respondent burden by 12,112 hours, bringing the total annual respondent burden to 34,401 hours. The changes in estimated annual respondent burden are summarized in Table B-12 (under section A12 below). All 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 Cannabidiol (CBD) for Pain Management	1	Chronic Pain Questionnaire (CPQ)	Annually, Summer Round
SNAP Participation	1	Income and Assets Questionnaire (IAQ)	Annually, Summer Round
VA Health Care Enrollment and Utilization	2	Health Insurance Questionnaire (HIQ)	Annually, Fall Round
Bowel Incontinence	5	Health Status and Functioning Questionnaire (HFQ)	Annually, Fall Round
Oral Health-Related Quality of Life (OHIP-5)	5	Health Status and Functioning Questionnaire (HFQ)	Annually, Fall Round

These changes include:

- 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 strategies¹. 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 work². 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 misuse³. 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 opioids⁴. However, the safety of long-term therapy has not been established⁵. As the use of CBD across the U.S. has increased for the management of pain, measures of pain treatment modalities should include CBD.

¹ [Interagency Pain Research Coordinating Committee](#)

² <https://www.cms.gov/files/document/mcbs-2018-survey-file-chronic-pain-infographic.pdf>

³ 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.

⁴ Ali, A., Arif, A. W., Bhan, C., Kumar, D., Malik, M. B., Sayyed, Z., Akhtar, K. H., & Ahmad, M. Q. (2018). Managing Chronic Pain in the Elderly: An Overview of the Recent Therapeutic Advancements. *Cureus*, 10(9), e3293. <https://doi.org/10.7759/cureus.3293>

⁵ 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/>

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 2024 Round 99, 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 2024 Round 99 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 One Item about Participation in the Supplemental Nutrition Assistance Program (SNAP).** The MCBS Income and Assets (IAQ) questionnaire is administered once per year during the Summer round. This revision adds one item to the IAQ about SNAP participation. Existing items in the IAQ collect information on financial well-being of Medicare beneficiaries, which is used to support analyses of effectiveness of various Medicare programs in reaching target populations and to improve outreach. IAQ also enriches analysis of inequity in healthcare access and use by providing information that is critical to understanding health outcomes, healthcare use, and spending down to Medicaid eligibility. As such, this section is used to support CMS' engagement in Executive Orders 13985⁶ and 13988⁷, issued in January of 2021, which called upon agencies to identify and work to redress inequities in their policies and programs that create barriers to equal opportunity and prevent and combat discrimination on the basis of gender identity and sexual orientation, respectively. To support this goal, CMS has released a variety of measures based on IAQ data, in the *Financial Well-Being of Medicare Beneficiaries* Public Use File (PUF)⁸. This table package is derived from the MCBS IAQ which currently includes the USA Economic Research Service's six standard questions on food security⁹. These questions ask whether respondents may have skipped meals or gone hungry due to lack of money. According to the *Financial Well-Being of Medicare Beneficiaries*, there are significant differences in food insecurity rates among Medicare beneficiaries. In 2020, 9.8 percent of White non-Hispanic beneficiaries living in the community were food insecure, compared with 25.2 percent of Black non-Hispanic beneficiaries and 28.7 percent of Hispanic beneficiaries. To further support alignment with Executive Orders 13985 and 13988, this revision seeks to add one question to the IAQ from the American Community Survey¹⁰ on SNAP participation which will allow CMS to enhance its understanding of food insecurity among Medicare beneficiaries and beneficiary experiences that directly influence health outcomes. The question on SNAP participation, in addition to existing IAQ items about residence in Section 8 housing and receipt of Supplemental Security Income (SSI), will also give CMS a more comprehensive picture of the various non-CMS programs that Medicare beneficiaries rely

⁶ <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/>

⁷ <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/>

⁸ <https://www.cms.gov/research-statistics-data-and-systems/research/mcbs/data-tables/2020-mcbs-financial-well-being-medicare-beneficiaries>

⁹ <https://www.ers.usda.gov/media/8282/short2012.pdf>

¹⁰ <https://www2.census.gov/programs-surveys/acs/methodology/questionnaires/2020/quest20.pdf>

on and further support CMS' alignment with Executive Orders 13985 and 13988. This item will be added to the IAQ beginning in Summer 2024 Round 99 where it will be fielded annually during the Summer round; this will result in an increase of 0.22 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 leakage¹¹. 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 hospitalization¹².

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 be related^{13, 14}. 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 them¹⁵.

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 Study¹⁶ and adapted to model the

¹¹ 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.

¹² 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>

¹³ 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>

¹⁴ 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/>

¹⁵ 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/>

¹⁶ 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

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 2024 Round 100 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 2024 Round 100 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 Five Items about Oral Health-Related Quality of Life.** This revision adds five items about oral health-related quality of life, the Oral Health Impact Profile instrument, known as OHIP5, to the HFQ. Older adults have a higher risk for poor oral health than any other age group because of insufficient dental insurance coverage, lack of access to oral health care, and prevalence of underlying health conditions that would be best managed by medical and oral health professionals working in tandem to provide coordinated care¹⁷. 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 older¹⁸. 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 nutritional problems, especially among the elderly, with highly negative effects on their quality of life¹⁹.

Being disabled, homebound, or institutionalized increases the risk of poor oral health²⁰. Older adults with the poorest oral health and lowest access to dental care tend to be those who are economically disadvantaged, lack insurance, and are members of racial and ethnic minorities. An Oral Health Surveillance Report from the Centers for Disease Control and Prevention (CDC) found that older non-Hispanic Black or Mexican American adults have two to three times the rate of untreated cavities as older non-Hispanic White adults. Older adults with less than a high school education have untreated cavities and complete tooth loss at nearly three times the rate of adults with at least some college education²¹.

¹⁷ National Institutes of Health. Oral Health in America: Advances and Challenges. Bethesda, MD: US Department of Health and Human Services, National Institutes of Health, National Institute of Dental and Craniofacial Research, 2021. <https://www.nidcr.nih.gov/research/oralhealthinamerica/section-3b-summary>

¹⁸ https://www.cdc.gov/oralhealth/basics/adult-oral-health/adult_older.htm

¹⁹ 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>

²⁰ 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

Since 2019, the MCBS has made improvements to survey content related to oral health, including improving the collection of dental utilization and cost information and adding items related to dry mouth and tooth sensitivity. These improvements allowed CMS to release the 2019 MCBS Report on Dental, Vision, and Hearing Care Services in September 2022, which provides estimates of dental, vision, and hearing care utilization by Medicare beneficiaries as well as comparisons of dental care use by certain sociodemographic characteristics²². They also allowed MCBS to support a variety of data needs associated with CMS Strategic Cross-Cutting Initiatives²³. Although the MCBS currently captures some oral health data, it does not provide a comprehensive measurement of a beneficiary's oral health functioning and quality of life. Measures for oral function, orofacial pain, orofacial appearance, and psychosocial impact make up the four dimensions of the Oral Health-Related Quality of Life (OHRQoL) and are needed to provide a more complete understanding of oral health among older adults and the impact of poor oral health on the overall health of Medicare beneficiaries. The Oral Health Impact Profile (OHIP) is currently the most widely used oral health-related quality of life (OHRQoL) instrument. The short OHIP5 has at least one indicator for each of the four dimensions and is specifically designed to provide a comparable level of analytic utility as longer scales with only five measures, supporting its content validity²⁴. These items performed well and were easily understood during a small cognitive testing effort (see Attachment 8). The OHIP5 instrument will be added to the HFQ beginning in Fall 2024 Round 100 where it will be fielded annually during the Fall round; this will result in an increase of 1.9 minutes for the Fall round interview.

- **Add Two Items about Veterans Affairs (VA) Health Care Enrollment and Utilization.** There is considerable interest in proposals to change Medicare in ways that can slow the growth of program spending. In conjunction with Medicare, supplemental insurance affects the point-of-services price of care to the beneficiary and, thereby, influences the beneficiary's access to health services. Supplemental insurance also influences the amount of money spent by the Medicare program, as it lowers or eliminates financial barriers to care. Because Medicare is not a fully comprehensive insurance program, the availability and coverage provided by supplementary insurance and its influence on the use and cost of care will be important for assessing Medicare expenditures and policy changes²⁵.

The MCBS collects information on all sources of supplemental insurance. This information is used by policymakers, including the Assistant Secretary for Planning and Evaluation (ASPE) Office of Health Policy and The Board of Trustees of the Federal

²¹ Centers for Disease Control and Prevention. Oral Health Surveillance Report: Trends in Dental Caries and Sealants, Tooth Retention, and Edentulism, United States, 1999–2004 to 2011–2016. US Dept of Health and Human Services; 2019.

²² <https://www.cms.gov/files/document/mcbs-data-highlight-utilization-dental-vision-and-hearing-care-services-2019.pdf>

²³ <https://www.cms.gov/files/document/cms-cross-cutting-initiatives-infographic.pdf>

²⁴ Naik A, John MT, Kohli N, Self K, Flynn P. Validation of the English-language version of 5-item Oral Health Impact Profile. *J Prosthodont Res.* 2016 Apr;60(2):85-91. doi: 10.1016/j.jpor.2015.12.003. Epub 2016 Jan 11. PMID: 26795728; PMCID: PMC4841723

²⁵ Chulis GS, Eppig FJ, Hogan MO, Waldo DR, Arnett RH. Health Insurance and the Elderly: Data from the MCBS. *Health Care Financing Review*; 1993: Volume 14, Number 3.

Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, to evaluate enrollment trends, estimate the number of beneficiaries who may be affected by program changes, and understand the impact of additional sources of coverage on Medicare expenditures and out-of-pocket costs paid by beneficiaries^{26,27}. Although the MCBS currently includes a question about whether a beneficiary has received health care services through the VA, this does not capture beneficiaries who may have had coverage through the VA but had not used VA health care services during the reference period. This method of collecting data, then, underestimates the number of beneficiaries covered by supplemental insurance available through the VA and limits policy makers knowledge of the alternatives available to Medicare beneficiaries to supplement their Medicare plans.

To address this gap, two items were adapted from the 2022 National Health Interview Survey (NHIS) to capture both VA health care utilization and enrollment on the MCBS starting in Fall 2024 Round 100²⁸. These items will be administered to beneficiaries who previously reported serving in the Armed Forces of the United States in the Enumeration Summary (ENS) section of their MCBS Baseline interview. The first item, which asks if the beneficiary received any care at a VA facility or any other health care paid for by the VA in the last 12 months, will replace an existing MCBS item about receipt of VA health care services, thereby creating better alignment between the MCBS and other federal surveys. While the existing MCBS item has the same intent, the parallel item from the NHIS extends the question to explicitly ask about receipt of care in non-VA facilities. The second item is new to the MCBS and asks beneficiaries who did not report VA health care utilization in the past 12 months if they have been enrolled in VA health care in the past 12 months. Incorporating these items on the MCBS starting in Fall 2024 Round 100 will allow CMS and stakeholders to understand the prevalence of VA coverage among Medicare beneficiaries, regardless of VA health care utilization. These items will be added to the Health Insurance Questionnaire (HIQ) beginning in Fall 2024 Round 100 where they will be fielded annually during the Fall round. Because the items will replace an existing item about VA health care utilization and will only be administered to veterans, the burden increase associated with these items is small; this will result in an increase of 0.1 minutes for the Fall round interview.

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

- **Streamline the COVID-19 Questionnaire (CVQ) in the Community Questionnaire.** The COVID-19 Questionnaire (CVQ) currently consists of about 30 questions taking about two minutes to administer each round. Starting in 2024, the CVQ section will be further streamlined, resulting in a deletion of about 20 items that are no longer relevant. Also, the administration schedule for the CVQ will be reduced—instead of asking the section three times a year (e.g., every round), it will be administered once per year. The 2024 CVQ section will focus on COVID-19 vaccination, testing, diagnosis, symptom

²⁶ ASPE Office of Health Policy. Medicare Beneficiary Enrollment Trends and Demographic Characteristics. March 2, 2022. Available from: <https://aspe.hhs.gov/sites/default/files/documents/f81aafbba0b331c71c6e8bc66512e25d/medicare-beneficiary-enrollment-ib.pdf>

²⁷ 2023 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Available from: <https://www.cms.gov/oact/tr/2023>

²⁸ <https://www.cdc.gov/nchs/nhis/2022nhis.htm>

severity, and prevention. These items have been realigned with other federal surveys that continue to collect data about the COVID-19 pandemic^{29,30,31}. Some items are also slightly re-worded to make them more appropriate and less burdensome for administration in 2024:

- o The COVID-19 testing series has been consolidated to ask about all types of COVID-19 tests in one series rather than asking separately about viral testing and antibody testing. Further, instead of asking a series of follow-up items about each type of COVID-19 test, including test result, wait time, and copayment, the revised series has been reduced. The beneficiary will first be asked if they have been tested for COVID-19 in the last year. If yes, they will be asked which type of test they received (e.g., via nasal swab, at-home test, or blood test) and the test result.
- o Rather than collecting full details for each COVID-19 vaccination dose, including vaccine date, manufacturer, and vaccine site, the revised CVQ will simply ask how many COVID-19 vaccine doses have been received by the beneficiary to convey an overall metric for vaccine uptake.
- o Instead of asking if the beneficiary has ever worn a mask as a COVID-19 prevention measure, the revised CVQ will ask how often the beneficiary masks in public to provide a more analytically useful measure of prevention behavior.

Fourteen total questions are being retained in the CVQ section. Only three items will be asked of all respondents; based on programmed skip logic, the remaining 11 items are only asked to a smaller number of respondents as a follow on to a previous question. Based on the results of timings tests, the streamlined CVQ is expected to take approximately 1.5 minutes on average to administer once a year in the Winter round. The removal of certain COVID-19 items and the change in the section's administration schedule will yield a significant reduction in respondent burden while still capturing information on topics of enduring importance related to COVID-19.

- **Streamline the COVID-19 Beneficiary (CV) section in the Facility Instrument and remove the COVID-19 Facility-Level (FC) section.** There are two sections in the Facility Instrument that have measures of COVID-19. The CV section, which is administered each round, asks whether beneficiaries have had a COVID-19 test, diagnosis, or vaccination since the last interview, and the FC section, which is administered once per year in the Fall round asks 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. Starting in 2024, the CV section will be reduced to a series on vaccination status to be asked annually in the Winter round. In addition, the FC section will be removed from the Facility instrument in its entirety. This will reduce the COVID-19 content in the Facility Instrument from about 40 items to five items.

²⁹ https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Survey_Questionnaires/NHIS/2022/EnglishQuest-508.pdf

³⁰ <https://www.cdc.gov/nchs/data/nhanes/2021-2022/questionnaires/COQ-L-508.pdf>

³¹ https://www2.census.gov/programs-surveys/demo/technical-documentation/hhp/Phase_3-7_Household_Pulse_Survey_ENGLISH.pdf

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

- **Update Respondent Materials.** To maximize outreach, CMS is adding one new item to the suite of existing respondent material (see Attachment 9). This new material is designed to increase understanding of the survey, particularly the Physical Measures (PXQ) questionnaire section, and thus improve participation. This material is used as a resource for interviewers when they encounter questions that beneficiaries ask about physical measures.

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 2024 Round 98	Summer 2024 Round 99	Fall 2024 Round 100	Total Annual Increase
Use of Cannabidiol (CBD) for Pain Management	CPQ	-	0.25	-	0.25 minutes
SNAP Participation	IAQ	-	0.22	-	0.22 minutes
Bowel Incontinence	HFQ	-	-	0.80	0.80 minutes
Oral Health Related Quality of Life (OHIP-5)	HFQ	-	-	1.90	1.90 minutes
VA Health Care Enrollment and Utilization	HIQ	-	-	0.10	0.10 minutes
Total Minutes Added		0 minutes	0.47 minutes	2.80 minutes	3.27 minutes
Net Annual Effect Increase in Community Burden					3.27 minutes

Table A-3 summarizes the decrease in burden associated with reductions in COVID-19 items in the Community and Facility instruments.

Table A-3: Decreased Burden Associated with Revisions to the Community and Facility instrument COVID-19 Questionnaire Sections

Community	Section	Winter 2024 Round 98	Summer 2024 Round 99	Fall 2024 Round 100	Total
Current COVID-19 Questionnaire Burden	CVQ	2.00	2.00	2.00	6.00 minutes
Revised COVID-19 Questionnaire Burden Due to Removal of Items and Change in Administration Schedule	CVQ	1.50	0	0	1.50 minutes

Community	Section	Winter 2024 Round 98	Summer 2024 Round 99	Fall 2024 Round 100	Total
Net Annual Effect Decrease in Community Burden		0.50	2.00	2.00	4.50 minutes

Beneficiary-Level COVID-19 Items in Facility Instrument

Facility	Section	Winter 2024 Round 98	Summer 2024 Round 99	Fall 2024 Round 100	Total
Current COVID-19 Questionnaire Burden	CV	2.00	2.00	2.00	6.00 minutes
Revised COVID-19 Questionnaire Burden Due to Removal of Items and Change in Administration Schedule	CV	0.33	0	0	0.33 minutes
Net Decrease in Beneficiary-Level Items					5.66 minutes

Facility-Level COVID-19 Items in Facility Instrument

Facility	Section	Winter 2024 Round 98	Summer 2024 Round 99	Fall 2024 Round 100	Total
Current COVID-19 Questionnaire Burden	FC	0	0	3.00	3.00 minutes
Revised COVID-19 Questionnaire Burden Due to Removal of Section	FC	0	0	0	0 minutes
Net Decrease in Facility-Level Items					3.00 minutes

Total Net Decrease Associated with Removal of COVID-19 Items in Facility Instrument

Facility	Winter 2024 Round 98	Summer 2024 Round 99	Fall 2024 Round 100	Total
Total Net Annual Effect Decrease in Facility Burden	1.66	2.00	5.00	8.66 minutes

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, the sample person’s first name can be filled for the duration of the interview when the interview is conducted with a proxy, rather than filling with “you/yours” as it would for an interview with the sample person. The 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 survey³². 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.

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 12th 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.

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

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. As an example, in this clearance, we retained important metrics while reducing burden by only asking COVID-19 items in the Community and Facility instruments once annually instead of three times per year.

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 March 20, 2023 (88 FR 16635). Seven comments were received expressing support for the addition of the oral health related quality of life (OHIP-5) measures to the HFQ portion of the MCBS in Fall 2024. Each of the commenters expressed the importance of measuring oral health related quality of life among Medicare beneficiaries and agreed that this information would help to inform oral health care practices and contribute to better oral health outcomes and overall well-being. In addition to supporting the measures, one commentator expressed interest in collaborating with CMS on the evaluation and application of these items. CMS appreciates the commenters' support.

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](https://www.cms.gov/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 06/22/2023 (88 FR 40827).

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 is 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-12c 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 (e.g., rounds) per respondent. The number of actual respondents who complete an interview changes every round and every year. 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.

Table B-12a shows the change in expected number of completes projected in this revision as compared to the previous full clearance revision for the 2023 MCBS. The expected number of completes in 2024 is lower than in the previous clearance by 983 interviews, thereby resulting in reduced annual burden estimates.

Table B-12a: Comparison of Estimated Number of Completed Interviews Projected in 2023 versus 2024 MCBS

Community Rounds	Estimated Number of Completes Projected in 2023 Full Clearance	Estimated Number of Completes Projected in 2024 Full Clearance Revision (Based on 2022 Actuals)	Difference
Winter Round Continuing	11,071	10,619	-452
Summer Round Continuing	8,020	7,880	-140
Fall Round Baseline	5,749	5,766	17
Fall Round Continuing	6,888	6,852	-36
Field Manager follow-up with 5% of Completed Interviews	1,586	1,556	-30
Total Change in Estimated Completed Community Interviews in 2024 Full Clearance Revision			-641

Facility Rounds	Estimated Number of Completes Projected in 2023 Full Clearance	Estimated Number of Completes Projected in 2024 Full Clearance Revision (Based on 2022 Actuals)	Difference
Winter Round Continuing Interview	951	799	-152
Summer Round Continuing Interview	714	593	-121
Fall Round Baseline Interview	202	209	7
Fall Round Continuing Interview	409	249	-160

Facility Rounds	Estimated Number of Completes Projected in 2023 Full Clearance	Estimated Number of Completes Projected in 2024 Full Clearance Revision (Based on 2022 Actuals)	Difference
Fall Round Baseline Interview for Cases with Admin Data	135	225	90
Fall Round Continuing Interview for Cases with Admin Data	273	267	-6
Total Change in Estimated Completed Facility Interviews in 2024 Full Clearance Revision			-342

Total Change in Estimated Completed Interviews in 2024 Full Clearance Revision: -983

Table B-12b shows the change in estimated interview length in this revision as compared to the previous full clearance revision for the 2023 MCBS (including the content additions and deletions included in this package). The 2024 estimated respondent burden (survey length) is based on actuals from 2022 when data collection returned to more stable metrics and predictability following a decline in the COVID-19 pandemic. The burden is reduced from prior estimates based on several factors. CMS continuously makes efficiencies in the way interviewers administer the MCBS, via more efficient survey programming and faster computing speed and advanced training methods that enables interviewers to proceed through complex sections of the questionnaire with greater ease. In addition, achieving a more stable field staff with greater experience administering the MCBS leads to interviewers becoming more familiar and adept at administering content over time. When reviewing estimated 2023 projected survey length compared with 2022 actuals, we find that the estimate in the OMB clearance was too high and therefore, have revised the survey length to be consistent with actual metrics from 2022. Note that using actual timing data will always involve a lag of two years due to the requirement to prepare the OMB clearance and submit it the year prior to data collection; that is, we cannot use actuals from 2023 as the data collection year is currently in progress.

Table B-12b: Comparison of Estimated Survey Length Projected in 2023 and 2024 MCBS Full Clearance Revision Requests

Community Questionnaire	Estimated Survey Length Projected in 2023 Full Clearance Revision	Estimated Survey Length Projected in 2024 Full Clearance Revision*	Difference in Hours
Winter Round Continuing Interview	72.30	60.10	-12.20
Summer Round Continuing Interview	81.40	57.87	-23.53
Fall Round Baseline Interview	82.80	65.90	-16.90
Fall Round Continuing Interview	104.80	75.30	-29.50

Facility Instrument	Estimated Survey Length Projected in 2023 Full Clearance Revision	Estimated Survey Length Projected in 2024 Full Clearance Revision*	Difference in Hours
Winter Round Continuing Interview	45.00	21.84	-23.16
Summer Round Continuing Interview	45.00	21.70	-23.30
Fall Round Baseline Interview—no CCN	64.70	37.00	-27.70
Fall Round Continuing Interview—no CCN	63.20	45.50	-17.70
Fall Round Baseline Interview for Cases with CCN	34.70	30.20	-4.50
Fall Round Continuing Interview for Cases with CCN	48.20	38.00	-10.20

Total Change in Expected Survey Length (Hours): -188.69

Using actual 2022 timing data to develop projections for the number of estimated completed interviews and survey length we estimate that our 2024 annual burden will be 34,401 hours for the survey, 12,112 hours less than the estimate in the current clearance. In sum, the reduction is due in part to the reduction of COVID-19 content as well as the use of the most current projections of number of completed interviews and survey length.

Table B-12c: Estimates of the Annual Respondent Burden in 2024

Community Rounds 98-100	Time Per Response	Number of Interviews	Expected Number of Completed Interviews Per Round	Burden Hours
Winter 2024 Round 98 Continuing Interview	60.10 minutes	1	10,619	10,637
Summer 2024 Round 99 Continuing Interview	57.87 minutes	1	7,880	7,600
Fall 2024 Round 100 Baseline Interview	65.90 minutes	1	5,766	6,333
Fall 2024 Round 100 Continuing Interview	75.30 minutes	1	6,852	8,599
FM Follow-up with 5% of Completed Interviews	5 minutes	1	1556	130

Facility Rounds 98-100	Time Per Response	Number of Interviews	Expected Number of Completed Interviews Per Round	Burden Hours
Winter 2024 Round 98 Continuing Interview	21.84	1	799	291

Facility Rounds 98-100	Time Per Response	Number of Interviews	Expected Number of Completed Interviews Per Round	Burden Hours
Summer 2024 Round 99 Continuing Interview	21.70	1	593	214
Fall 2024 Round 100 Baseline Interview	42.00	1	209	146
Fall 2024 Round 100 Continuing Interview	40.50	1	249	168
Fall 2024 Round 100 Baseline Interview--Admin Data	30.20	1	225	113
Fall 2024 Round 100 Continuing Interview--Admin Data	38.00	1	267	169

Rounds 98-100	Expected Number of Completed Interviews Per Round	Burden Hours
Total Expected Number of Completed Interviews Annually	35,015	
Total Annual Burden Hours		34,401
Total Estimated Burden Hours – Rounds 98-106 (3 Years)		103,203

Below provides a summary of the annual burden change from the current clearance, reflecting the increased burden of adding 14 new questions, and the decreased burden of reducing COVID-19 items in the Community and Facility instruments and using the most current survey actuals for projected interview completes and survey length.

Total annual burden hours – current 2023 clearance	46,513
Total annual burden hours – revised 2024 clearance	34,401
Total annual burden hours – difference	(12,112)

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 2023³³) and multiplied it to the Total Annual Hours for Rounds 98-100 (34,401), for a Total Annual Cost Burden in terms of dollars of roughly \$249,406.34.

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.

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

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

Option Year 1 (May 1, 2022-April 30, 2023): Survey development, operations, processing and analysis: \$23,297,759.23³⁴

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

CMS personnel involved in MCBS include approximately 11 FTEs broken out by paygrade or paygrade range in Table B-14.

Table B-14: CMS Personnel

Grade	FTE	2023 Annual Salary	Cost to Government ³⁵
GS9-GS12	1.0	\$79,578	\$79,578
GS13 step 5	5.0	\$126,949	\$634,745
GS14 step 5	4.0	\$150,016	\$600,064
GS15 step 5	1.0	\$176,458	\$176,458
			\$1,490,845

CMS staff costs are approximately \$1,490,845. In addition, staff travel is budgeted for \$8,000. The MCBS releases its documentation as downloadable files on its public website and on CD Rom thus eliminating its printing budget. Thus, in-house CMS cost will be \$1,498,845.

A15. Explanation for Burden Changes (Program Adjustments)

While this revision includes the addition of 14 questions that result in a burden increase of 3.27 minutes, reducing COVID-19 content will offset this small increase. There is a net reduction of 4.5 minutes for the Community questionnaire and 8.66 minutes for the Facility instrument. Further, the use of the most current survey actuals for projecting number of interview completes and survey length will contribute to a reduction in overall burden. Specifically, as noted earlier, the following changes are requested:

Changes that will **increase** respondent burden:

- 0.47 minutes of burden will be added to each Summer interview beginning in Summer 2024 due to the addition of one new item in CPQ related to the use of CBD for pain management and one new item in IAQ related to SNAP participation.
- 2.8 minutes of burden will be added each Fall round starting in Fall 2024 due to the addition of five items related to bowel incontinence and five items related to oral health-related quality of life in the HFQ as well as two items related to VA health care enrollment and utilization in the HIQ.

Changes that will **decrease** respondent burden:

³⁴ Future awards are based on execution of option years and funding availability.

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

- Deletion of 20 COVID-19-related items and a change in the section’s administration schedule from round-based to annual will **remove 4.5 minutes from the Community instrument annually** (2 minutes each Summer and Fall round and 0.5 minutes in the Winter round).
- Deletion of about 35 COVID-19 items from the Facility instrument via the removal of the COVID-19 Facility-Level (FC) section and reduction of items in the COVID-19 Beneficiary-Level (CV) section will also remove **8.66 minutes from Facility data collection annually** (1.66 minutes in the Winter round, 2 minutes in the Summer round, and 5 minutes in the Fall round).
- Use of data collection actuals from the most recent year available – 2022—provide a more accurate representation of projected number of survey completes and survey length in 2024 and beyond. Using updated actuals accounts for the remaining reduction in burden hours.

Net impact to respondent burden:

- As a result, the total burden has decreased to 34,401 from the previously approved total burden of 46,513. This is a net decrease of 12,112 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 98 (Winter 2024) through Round 106 (Fall 2026). See Table B-16a for data collection rounds and plans for data dissemination.

Table B-16a: Annual schedule for information collection and dissemination, July 2023 - October 2028

Data collection schedule

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
01/07/2026	Data collection starts for Winter 2026 Round 104
05/06/2026	Data collection starts for Summer 2026 Round 105
07/22/2026	Data collection starts for Fall 2026 Round 106

Data dissemination schedule

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	Survey File Microdata Public Use File for 2021 data.
01/15/2024	Cost Supplement 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.
01/15/2025	Cost Supplement 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.
01/15/2026	Cost Supplement 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.
01/15/2027	Cost Supplement 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.
01/15/2028	Cost Supplement Microdata Public Use File for 2025 data.
07/15/2028	Limited Data Set available for 2026 Survey File.
10/15/2028	Limited Data Set available for 2026 Cost Supplement File.
10/15/2028	Microdata Public Use File for 2026 data.
01/15/2029	Cost Supplement Microdata Public Use File for 2026 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.