

**Testing Experience and Functional Tools: Functional
Assessment Standardized Items (FASI) Based on the CARE
Tool**

Paperwork Reduction Act Submission

Part A: Justification

Prepared for:

Kerry M. Lida, PhD
Centers for Medicare & Medicaid Services
Disabled and Elderly Health Programs Group
Mail Stop S2-14-26
7500 Security Boulevard
Baltimore, MD 21244-1850

Revised by:

Lisa Alecxih
The Lewin Group

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FUNCTIONAL ASSESSMENT STANDARDIZED ITEMS (FASI)

PAPERWORK REDUCTION ACT SUBMISSION

PART A: Justification

Revised by: Lisa Alecxih, MPA

Federal Project Officer: Kerry M. Lida, PhD

The Lewin Group

CONTENTS

BACKGROUND	1
JUSTIFICATION	3
1. NEED AND LEGAL BASIS	3
2. INFORMATION USERS	4
3. USE OF INFORMATION TECHNOLOGY	5
4. DUPLICATION OF EFFORTS	5
5. SMALL BUSINESSES	5
6. LESS FREQUENT COLLECTION	5
7. SPECIAL CIRCUMSTANCES	5
8. FEDERAL REGISTER/OUTSIDE CONSULTATION	6
8.1 60-day Federal Register Notice	6
8.2 Efforts to Consult Outside Agency	6
9. PAYMENTS/GIFTS TO RESPONDENTS	9
10. CONFIDENTIALITY	9
11. SENSITIVE QUESTIONS	10
12. BURDEN ESTIMATES (HOURS & WAGES)	10
13. CAPITAL COSTS	12
14. COST TO FEDERAL GOVERNMENT	12
15. PROGRAM AND BURDEN CHANGES	12
16. PUBLICATION/TABULATION DATES	14
16.1 Field Test Dates	14
16.2 Data Analysis Dates	14
17. EXPIRATION DATE	14
18. CERTIFICATION STATEMENT	14
REFERENCES	14

LIST OF TABLES

1. Estimated annualized burden hours	11
2: Estimated annualized cost burden	11

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Background

The Centers for Medicare and Medicaid Services (CMS), as part of the National Testing Experience and Functional Assessment Tools (TEFT) demonstration, tested the use of functional assessment standardized items (FASI) among community-based long term services and supports (CB-LTSS) populations. The TEFT initiative built on the national efforts to create electronically exchangeable data across providers and the caregiving team to develop more person-centered services under the Medicare and Medicaid programs.

After conclusion of the field test, states have begun implementing the related FASI performance measures and the FASI team continues to recruit additional states. While the team has not conducted data collection since the FASI field test in 2017, and that there are no concrete immediate plans to collect new data, new data collection to support measure re-endorsement activities due in 2025 will be needed. The data collection may also need to be conducted sooner if significant changes are made to the measures' technical specifications, in the interim. Due to the uncertainty on when data collection may need to be done, an extension of the existing package and a subsequent revision would facilitate expedient resumption of the data collection and testing efforts than would a new submission, especially given the quick turnaround time for activities (such as National Quality Forum measure endorsement) which depend on the data collection.

FASI is based on a subset of the July 27, 2007 (72 FR 144) Continuity Assessment Record and Evaluation (CARE) items which are now included in post-acute setting Federal assessment forms for nursing facilities - Resident Assessment Instrument (RAI) Minimum Data Set (MDS), Inpatient Rehabilitation Facilities Patient Assessment Instrument (IRF-PAI), and Long Term Care Hospitals Continuity Assessment Record & Evaluation (CARE) Data Set (LCDS) to measure function in a standardized way. The FASI items include the standardized mobility and self-care items included in the MDS, IRF-PAI, and, LCDS as well as some additional mobility items appropriate to measuring independence in the community and personal preferences or goals items related to function. Also included are certain instrumental activities of daily living and some modified caregiver assistance items from the Home Health Outcome and Assessment Information Set (OASIS) tool. A few additional items to describe the populations' age, gender, and geographic area of residence are also included. Use of the same items to measure functional status in nursing facilities and community-based programs will help states report on their rebalancing efforts. Also, because these items will have electronic specifications developed by CMS, they can assist state efforts to develop exchangeable electronic data to follow the person across services and estimate total costs as well as measure functional status across time. The complete FASI set is included in this information collection request.

The TEFT FASI initiative tested the application of the standardized items' reliability and validity when used across home and community-based service (HCBS) populations. The targeted subpopulations included:

- Older adults (individuals aged 65 and over),
- Younger (aged 18 to 64) adults with physical disabilities,
- Adults of all ages with:
 - Intellectual /developmental disabilities (ID/DD),

- Severe mental illness (SMI), or
- Traumatic brain injury (TBI).

The results of the FASI initiative provided states with reliable and standardized items for measuring function that can be used for multiple purposes. First, standardizing commonly collected items across programs within the state will ease data collection burden for both the program and participants. Second, standardized data can be used across states to evaluate the complexity of the populations covered under different state policies and consider the impact of these variations on access to care. Third, standardizing the state elements with those in the Federal assessment tools used in the nursing facilities will allow comparison of the institutional and community-based populations to examine the cost-effectiveness of the home and community-based waivers in the Medicaid program.

The FASI items were developed based on input from three Technical Expert Panels (TEP) comprised of representatives from each of the five population groups' communities, the participating states, and experts in functional measurement. The first TEP was held September 2014, the second TEP was held October 2015, and the third TEP in November 2017. The TEPS reviewed:

- the existing standardized function items in the CARE item set for appropriateness for the target HCBS populations (date);
- proposed new items for the HCBS population that would expand the measurement of mobility in the community and identify personal preferences for functional status (date);
- existing OASIS items on instrumental activities of daily living and caregiver needs that are already in CMS' assessment data library for appropriateness for the HCBS populations (date); and
- Round 1 Field testing results and recommended adjustments.

The TEFT FASI project found the FASI Set to be reliable (including inter-rater reliability) and valid with each of the target subpopulations. Five of the states involved in the FASI component of the TEFT project voluntarily selected items from the FASI Item Set to compare to existing assessments and understand assessor and participant experiences in order to make decisions regarding incorporation of the FASI Set into their eligibility processes.

The FASI Set is not intended to provide all of the items needed to develop a comprehensive, universal, or uniform assessment tool; only those related to function. However, as states build their respective universal/uniform assessment tools, the FASI items will provide reliable and valid items they can use in their efforts.

As CMS continues to standardize its approach for measuring health and functional complexity, the [Data Element Library \(DEL\)](#) provides a centralized resource for CMS assessment instrument data elements (e.g. questions and responses) and their associated health information technology (IT) standards. CMS plans to add the FASI Item Set to the DEL.

Abstracting data from the Round 1 testing, Truven Health Analytics and George Washington University developed two HCBS FASI measures to submit for endorsement to the National Quality Forum (NQF):

- Alignment of individuals' services with needs as documented by FASI -- Percentage of individuals 18 years or older who received community-based LTSS with documented needs determined by a FASI and who have at least three personal priorities related to self-care, mobility, or instrumental activities of daily living functional needs within the reporting period
- Alignment of person-centered service plans with functional needs as determined by FASI -- Percentage of individuals 18 years or older who received community-based LTSS with documented needs as determined by the FASI assessment and documentation of a person-centered service plan that addressed functional needs

This 2022 information collection request requests an extension to the existing information request and with no changes to the collection instruments.

Justification

1. Need and Legal Basis

The Patient Protection and Affordable Care Act (ACA), Section 2701, called for a demonstration program for testing Experience of Care and Functional Assessment Tools (TEFT) in CB-LTSS. Thus, the TEFT FASI Set, developed through the TEFT project, directly supported CMS's implementation of the ACA.

There is a strong need for standardized assessment and quality measurement in CB-LTSS. In its report to Congress, the Commission on Long-Term Care (2013) articulated a number of principles and recommendations, as well as a vision, for transforming the delivery of LTSS.¹ Regarding standardized assessment, the Commission recommended that:

- A standardized assessment tool should be used to “produce a single care plan across care settings for an individual with cognitive or functional limitations” (page 43).
- LTSS should be provided in a person- and family-centered manner, “where high-quality, financially-sustainable medical and social services and supports” meet “the heterogeneous needs, preferences, and values of individuals with cognitive and functional limitations” (page 36).
- LTSS should be integrated “with medical and health-related care, including effective management of transitions between one type or level of care and another” (page 36).

¹ <http://www.ltccommission.org/>

The Commission recognized that a “common or standard assessment tool across programs and services enables better alignment and coordination of care provided to the same individual from multiple programs and funding sources and helps ensure consistent evaluation of need and provide data for evaluation of program performance and quality of care” (page 43). FASI items provide the standardized items to measure functional status consistently across programs and states.

Leading consumer advocacy organizations have advanced similarly strong calls for standardized assessment. AARP, for example, urged that federal and state governments should use standardized assessments to determine the appropriate type and intensity of service in a consistent manner. They also noted that states that have achieved greater success in transforming their LTSS system have implemented, or are in the process of designing, standardized assessment tools (AARP, 2014).

States are also demonstrating the need to standardize assessment as evidenced by the actions they are taking to implement it (Atkins and Gage, 2014; Black and Leitch, 2012; Shirk, 2009). Their reasons for implementing standardized assessment are consistent both among the states and with the rationale provided by the Commission on Long-Term Care and AARP. As Black and Leitch (2012) point out, from a practical, programmatic standpoint, states are using standardized assessment to: (1) integrate health and medical services with LTSS, (2) increase the quality of client-centered services, (3) better plan and manage services and costs, and (4) better manage staff and increase operational efficiencies.

2. Information Users

This submission requests extension of the FASI PRA package described above. Currently, in implementation, information users of the FASI items will be States participating in different programs or federal agencies conducting demonstration programs.

For the data collection related to the existing FASI PRA, all data were maintained in a secure environment at Qlarant and GWU, and access was limited to analysts working on this project. Personally identifiable information (PII), such as last name, first name, mailing address, and contact information was used by the states and the data collectors to identify the sample and enroll participants. These data were protected by Qlarant using approved data security methods. These identifying items were stripped before the data were transferred to GW for analysis. No PII data were required for analysis since the data will not be linked to claims or any other data sources. Data were aggregated by HCBS program area and may be stratified by age groups, but no specific dates of birth or other identifiable data will be used in the analysis. During the expected data collection, the FASI team will maintain these standards of privacy and protections.

The results of the reliability and validity testing were provided to CMS in a FASI Field Test Report. The report included aggregate data and analytic findings only; no individual-level information will be provided. In response to the analyses of reliability and validity, Truven Health Analytics recommended changes to individual TEFT FASI Set, to be made prior to releasing the TEFT FASI Set for use by the states. Eventually, after approval from CMS, the FASI Field Test Report was released to the public.

3. Use of Information Technology

The existing PRA, to which we seek extension, addresses data collection that allows testing of the validity and reliability (i.e., field test) of the standardized items that comprise the FASI Set. The FASI Set is collected by assessors using an electronic PDF form to collect the data. In line with this approach, during future data collection, assessors will use their professional laptops on which they currently collect assessment data. The data will be uploaded to an exclusive project data storage system using a secure file transfer protocol and maintained in a secure application as described in the security plan.

Signatures of consumers being assessed (respondents) and assessors will not be collected. Individual assessors collect signed consent documentation from their clients and maintain the information in their locked offices where they hold other PII data. .

4. Duplication of Efforts

Collection of FASI data does not duplicate any other effort and the data cannot be obtained from any other source. Items contained in existing assessment instruments used in state HCBS programs differ in their definitions and rating scales, preventing comparison of consumer populations across HCBS programs and states. The FASI Set are designed to standardize the data collected across settings, populations, programs, and states. There is no requirement for the states to use FASI Set beyond this demonstration project.

All state Medicaid programs collect similar data on many of the domains of the FASI Set. FASI data collection facilitates testing item reliability and validity and standardization of items FASI items across populations, states, and programs within states and Federal standardized items collected in nursing facilities and home health agencies, as well as other post-acute care (PAC) settings. This enables cross-setting utility, across populations and programs, and tracking by states of changes in the status of beneficiaries or assessment of the quality of providers or programs.

5. Small Businesses

The collection of FASI data does not impact any small businesses or other small entities.

6. Less Frequent Collection

Periodic (approximately every 5 years) data collection in this study provides CMS with essential information to further develop performance measures made available to states for use in their Medicaid HCBS programs. The ability to collect information about individuals needing LTSS in a consistent, valid, and reliable manner fills an information gap, and enables policymakers to make informed decisions about Medicaid LTSS programs, eligibility, services, and costs moving forward.

7. Special Circumstances

Collection of FASI data relies on instruments validated to reliably ensure sensitivity to functional status changes. However, it is not intended to produce results that can be generalized to the universe of study. Also, it does not:

- Require respondents to report information to the agency more often than quarterly;
- Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Require respondents to submit more than an original and two copies of any document;
- Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Does not require the use of a statistical data classification that has not been reviewed and approved by OMB;
- Include any pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Require respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

8.1 Federal Register Notice

The 60-day notice published in the Federal Register on January 17, 2023 (88 FR 2625). Comments must be received by March 20, 2023.

8.2 Efforts to Consult Outside Agency

CMS authorized three Technical Expert Panels (TEP). The first TEP convened by RTI in September 2014 included individuals with the following attributes, areas of expertise, and perspectives:

- subject matter expertise in HCBS;
- broad knowledge of the process to develop standardized assessment items;
- knowledge of assessment domains that are relevant to eligibility determination, the need for services, level of care determination, service planning, and quality measurement;
- experience with the modification of existing CARE assessment items;
- broad knowledge of performance measurement, quality improvement, and health disparities; and
- ability to represent state Medicaid programs, provider, consumer, or payer perspectives.

At the meeting the TEP reviewed the set of unmodified, modified, newly developed, and excluded standardized assessment items and provided expert input on the appropriateness of the

items in each of these categories. They also provided insights on the practical issues that must be addressed in field testing these items. Lastly, the TEP discussed key issues that CMS and RTI identified in advance including:

- pros and cons of direct observation versus interviewing clients,
- issues related to the response set for ADLs, and
- the best way to measure mobility, pressure ulcer, and cognitive impairment concepts in the HCBS population.

Revisions to the TEFT FASI Set were made following the TEP meeting. TEP members were offered the opportunity to review and comment on the revised materials. Based on these comments and discussions with CMS, RTI made several rounds of revisions to the FASI items prior to conducting cognitive interviews.

A second TEP was held by Truven Health Analytics, the Post-Acute Care Center for Research and George Washington University on October 28, 2015. This TEP reviewed the CARE-based function items which had since been added to the Federally-required assessment tools (MDS, IRF-PAI, and LTCH-CARE) and the CMS data element library. The TEP reviewed those items and response scales for applicability to the HCBS populations. They also reviewed the additional mobility, instrumental activities of daily living, personal preferences, and caregiver assessment items not yet added to the Federal assessment tools.

This TEP focused on two sets of items each with their respective questions for input:

- 1) The standardized function items in the CMS data elements library
 - Are all the standardized items relevant to include in the HCBS FASI item set?
 - Is the rating scale appropriate for HCBS populations?
 - Is the data collection mode appropriate for HCBS populations?
 - What guidance is needed to ensure the assessment reflects “usual performance”?
- 2) Additional items to standardize and align to CMS data initiatives
 - Should items on prioritizing person’s preferences for functional status be included?
 - Should additional mobility items be included to better reflect mobility in the community?
 - Should Instrumental Activities of Daily Living be included?
 - Should items on caregiver support needs be included?

This TEP meeting provided very useful information for the FASI team’s refinement of the proposed item set. The TEP commended the language in the standardized items and response codes and found the introductory statements on the coding page that referred to the person’s ability to *safely* complete the task to be critical. The TEP members also commented that the coding structure was clear, understandable, and focused on the person’s ability. Commenters clearly felt it important to include a wide range of inputs in determining the person’s ability, including the observed performance, the person’s input and input from the range of people interacting with the person. In developing the training materials, they felt it will be important to highlight what information the assessor should use in scoring the assessment. The TEP echoed

the team's emphasis on the voice of the person being assessed and those of others who are interacting regularly with the person in the community as being critical during the process.

The TEP also commented on the need for additional devices to be included in the device use list. As a result, the Truven Health Analytics team reviewed assessment tools from various HCBS programs to identify items to add to the standardized FASI list.

The proposed additional mobility items also were well-received by the TEP. Follow-up occurred with one of the TEP members who was asked whether additional mobility items were needed. The feedback was that the proposed set covers a wide range of ability, particularly given the inclusion of walking on uneven surfaces in the standardized mobility item section.

The inclusion of Instrumental activities of daily living (IADLs) was identified as extremely important, as was the information on the available caregiver and their needs. Additional items could be included in future work.

Following the two TEPs, the FASI items were pilot tested in a small alpha test to gain input from outside assessors regarding their usability, feasibility, and appropriateness for the five waiver populations. The alpha test was conducted over a three week period in December 2015. The state of Connecticut agreed to host the alpha test and identified five state assessors to conduct the alpha test. Four of the assessors identified 2 clients each while the fifth assessor identified one client to participate in the alpha test. Following IRB approval by GWU, and completion of business associate agreements between Truven Health Analytics and each of the assessors, the assessors were trained on the data collection protocol. Each were given materials to gain participant consent, and a \$25 gift card to provide clients as a thank you for participating in the alpha test. Assessors were paid \$500 each for participating in the training, data collection and a cognitive interview following data collection.

The alpha test provided valuable input on the proposed FASI data collection form. The layout of the items was modified. Additional codes were recommended for the IADL items and the caregiver assistance items. Feedback was provided on the use of the Federal standardized function items with the HCBS populations. The assessors praised the clarity of the items and the response codes for the mobility and self-care items. They particularly liked the inclusion of items asking the participants about their goals and having those items embedded in each subsection of items so they could focus the responses on each area of activity (i.e., mobility, self-care, IADLs). They also commented that the proposed items were easier to use to assess client needs than the items the state currently uses. They did propose adding an item to also measure whether the client's status had changed in the past 30 days, in addition to the original item asking about the client's usual performance over the past 3 days. These proposed recommendations have been incorporated in this submission.

The third TEP held by Truven was convened in November 2017 to review the FASI field test results. The FASI team reviewed the evidence on the reliability and validity of the FASI set, elicited feedback from key stakeholders regarding revisions to the FASI and considered next steps in proposing quality performance measures based on the FASI set. For the entire FASI set, the TEP recommended that responses over the past three days, as well as those over the past month, should be retained. Although most individuals did not experience fluctuations in their

need for assistance between the past three days and the past month, TEP members believed that it was important to retain scoring items relative to this assessment reference period when it occurred. The TEP also recommended updating several instrumental activities of daily living items to better reflect the use of current technology in completing everyday activities. Specific changes included:

- Assessor instructions for the completion of the Priorities sections were modified to promote the identification of at least one personal priority. Also, the Priorities sections for Living Arrangement and Caregiver Assistance and Availability were separated into two distinct subsections.
- Additional examples were added to the instrumental activities of daily living: simple financial management to include online/mobile bill pay, banking, or shopping.
- Crutches and prosthetics were deleted from the list of assistive devices, and six devices were added: reacher/grabber, sock aid, raised toilet seat, glucometer, continuous positive airway pressure (CPAP), and oxygen concentrator.
- Two duplicative item

9. Payments/Gifts to Respondents

No payments are planned to respondents at this stage. When data collection resumes, Lewin does not anticipate paying respondents to participate in the FASI data collection.

10. Confidentiality

Lewin, GWU, Qlarant, and CMS will keep all FASI data confidential. Only authorized staff at CMS and the Qlarant team will have access to respondents' data. Data will be stored in a secure format that meets all federal privacy guidelines. Data will be collected using a secure internet-based platform for secure data transmission. The internet-based electronic system will be password protected with access limited to project staff. Individuals and organizations will be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose. In compliance with federal requirements, the FASI instrument is listed under SORN 09-70-0569.

Individuals and organizations contacted will be further assured of the confidentiality of their replies under 42 U.S.C. 1306, and 20 CFR part 401, 4225 U.S.C. 552a (Privacy Act of 1974), and OMB Circular No.A-130. In instances where respondent identity is needed, the information collection will fully comply with all respects of the Privacy Act.

Some states have mandatory reporting laws for vulnerable adults, including elders and persons with disabilities, which require reporting of suspected abuse and neglect. In field test states where these statutes apply to interviewer staff, respondents will be clearly informed of this fact prior to data collection. Interviewer staff will comply with all relevant federal and state statutes regarding mandatory reporting.

11. Sensitive Questions

Some respondents may view certain questions as sensitive, particularly questions related to disability, including cognitive status and ability to perform ADLs and legal status (e.g., whether the person has a legal guardian). These variables are all critical to the FASI assessment. The purpose of the FASI Set is to identify the health and abilities of individuals to determine whether the person has a qualifying level of need for receiving services, identify the level of assistance required, and develop plans to accomplish those goals while meeting their needs. Knowing whether the person has a legal guardian is important to ensure that information flows from and to people with a need and a legal right to be involved. These questions are similar to those asked in other assessment tools used by state Medicaid programs for similar purposes and for similar purposes in other health care settings, and are of recognized value.

Information from these sensitive questions, during data collection, will be used to assess the reliability and validity of the items. Currently, during the implementation phase, some state Medicaid HCBS programs are using these items to determine individuals' eligibility for services, the general level of services to be provided, the types and quantity of specific services to support the identified needs, and to measure the quality of outcomes for individuals and for programs as a whole.

12. Burden Estimates

The burden response estimates for the past data collection conducted by Lewin are shown in *Table 1* (time) and *Table 2* (costs). The cost calculation has been updated using current wage rates, although no actual burden response or cost estimates are associated with this FASI PRA extension submission.

Under the data collection managed by the Lewin team, the goal is to complete assessments on individuals in the following five subpopulations: older adults (aged 65 and older), younger (aged 18 to 64) adults with a physical disability, and adults of all ages with ID/DD, SM, or TBI). We expect to complete a minimum of 314 assessments for each subpopulation, resulting in a sample size of 1,570 individuals (5 subpopulations x 314 assessments).

The FASI items were pilot tested to collect information on burden. The average length time to complete each of the survey sections ranged on average from 4 minutes to 6 minutes, and a median of 5 minutes per section. The total estimated burden of 30 minutes is based on the sum of the median times to complete for each section. Respondents included five assessors with each one assessing two clients, with the exception of the respondent working with the aged recipient who only assessed one person bringing the total pilot test sample to 9 clients. The cognitive test showed ease of administration, including a perception that these items were simpler assessment items than similar ones found in existing state assessment tools for measuring the same concept. Responses were fairly consistent in burden across populations, although the person assessing the severely mentally ill clients averaged an extra 5 minutes on the mobility items.

Table 1: Estimated annualized time (hours)

Section name	Number of respondent	Average Number of minutes per respondent	Median Minutes per respondent	Total burden hours
Section A: Person Demographics	1,570	4	5	130.83
Section B1: Self Care	1,570	5	5	130.83
Section B2: Mobility	1,570	6	5	130.83
Section B3: IADLs	1,570	5	5	130.83
Section C: Assistive Devices	1,570	4	5	130.83
Section D: Support / Caregiving	1,570	4	5	130.83
Total	1,570	28	30	785

Source: Truven Health Analytics estimates based on pilot study.

Table 2: Estimated annualized cost (\$)

Section name	Number of respondents	Total time (hr)	Mean wage rate (\$/hr)	Total cost (\$)
All sections	1,570	785 (1570 x 0.5 hr)	32.49	25,504.65
Total	1,570	785	32.49	25,504.65

Source: Truven Health Analytics and The Lewin Group estimates.

We anticipate that the actual cost to individual questionnaire respondents will be minimal as these will be conducted as part of their previously scheduled case management visits. Interviews will be scheduled with individuals at a time and location convenient for them. This scheduling should avoid concerns about transportation costs and about lost wages for those who work. Other than their time, respondents will bear no additional costs.

We are attaching the consent form to this package, but we are not setting out the burden for completing this form since we believe the instrument does not meet the definition of “information” under 5 CFR 1320.3(h)(1).

As shown in **Table 2**, the estimated seasonally adjusted hourly earnings for all employees on private nonfarm payrolls in September 2022 was \$32.49/hour (U.S. Bureau of Labor Statistics, 2022). Thus, the total estimated burden cost will be \$ 25,504.65 assuming 1,570 completed assessments. An estimate of \$32.49 per hour allows for inflation and represents a conservative

estimate of the wages of the respondents, the majority of whom are likely not employed as a result of their age and/or disability, or who may be employed in low-wage situations.

Information Collection Instruments/Guidance Documents

Testing Experience and Functional Tools (TEFT), Functional Assessment Standardized Items (FASI) (No changes)

Consent Form (revised to remove reference to “gift card” as a benefit for participation)

Although we are attaching the consent form to this package, we believe the instrument is exempt from the requirements of the PRA since it does not meet the definition of “information” as defined under 5 CFR 1320.3(h)(1). The form is attached as a courtesy.

13. Capital Costs

There are no additional capital costs to respondents or to record keepers.

14. Cost to Federal Government

- No financial costs are associated with the extension request.

15. Program and Burden Changes

Relative to the most recent OMB approval (April 2020), No changes are proposed for the FASI Set and instructions:

Minor changes to other documents are listed below:

CMS-10243 – Supporting Statement A , Background p.1.

Addition: After conclusion of the field test, states have begun implementing the related FASI performance measures and the FASI team continues to recruit additional states. While the team has not conducted data collection since the FASI field test in 2017, and that there are no concrete immediate plans to collect new data, new data collection to support measure re-endorsement activities due in 2025 will be needed. The data collection may also need to be conducted sooner if significant changes are made to the measures’ technical specifications, in the interim. Due to the uncertainty on when data collection may need to be done, an extension of the existing package and a subsequent revision would facilitate expedient resumption of the data collection and testing efforts than would a new submission, especially given the quick turnaround time for activities (such as National Quality Forum measure endorsement) which depend on the data collection.

CMS-10243 – Supporting Statement A, Background p.2-3

Deletions:

- “Based on a TEP’s review of the Round 1 Testing results changes to the FASI Item Set including clarifying instructions to assessors for completing personal priorities

sections, enhancing examples of simple financial management, revising the list of assistive devices, and removing two duplicative items from the caregiver assistance section”.

- “The Round 1 burden was updated with more recent wage data while Round 2 will not be conducted”.
- “This data collection effort amends the TEFT FASI data collection effort identified above.”
- “Individual-level data will be collected using the FASI Set. The first data collection effort will be conducted by The Lewin Group and its subcontractors George Washington University and Qlarant, working with state-identified assessors to collect data that can be analyzed to evaluate the reliability and validity of the FASI items when used with the five waiver populations and to test performance measures. Assessors will conduct functional assessments in client homes using the FASI Set. They will enter the data into an electronic PDF data collection tool. The data will be uploaded on a weekly basis using a secure electronic transfer file. Qlarant will send the de-identified field test data to the George Washington University for reliability and validity analysis”

CMS-10243 – Supporting Statement A , Information Users p.4

Deletion: “Personally identifiable information (PII), such as last name, first name, mailing address, and contact information will be stripped before the data are transferred to GW for analysis.”

CMS-10243 – Supporting Statement A , Use of Information Technology p.4

Deleted: “Individual assessors collect signed consent documentation from their clients and maintain the information in their locked offices where they hold other PII data”

CMS-10243 – Supporting Statement A ,Confidentiality, p.9

“Addition: In compliance with federal requirements, the FASI instrument is listed under SORN 09-70-0569”.

CMS-10243 – Supporting Statement A , Burden estimates p.10

Addition: “The cost calculation has been updated to estimate cost using current wage rates, although no actual burden response or cost estimates are associated with this FASI PRA extension submission.”

FASI Consent Assessment Forms 508

Deletion: “If you agree to take part in this research study, we will provide you with a gift card for your time and effort. You will be asked to acknowledge receipt of this gift card on a separate form.”

16. Publication/Tabulation Dates

16.1 Field Test Dates

- TBD.

16.2 Data Analysis Dates

- TBD.

17. Expiration Date

The OMB expiration date will be displayed on all materials, as appropriate.

18. Certification Statement

CMS does not seek exemption to the certification statement identified in “Certification for Paperwork Reduction Act Submission” of OMB Form 83-1.

References

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