

**July 22, 2016**

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

**Paperwork Reduction Act Submission  
Part A: Justification**

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TESTING EXPERIENCE AND FUNCTIONAL TOOLS: FUNCTIONAL ASSESSMENT  
STANDARDIZED ITEMS (FASI) BASED ON THE CARE TOOL

PAPERWORK REDUCTION ACT SUBMISSION

PART A: JUSTIFICATION

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Truven Health Analytics

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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, is testing the use of functional assessment standardized items (FASI) among community-based long term services and supports (CB-LTSS) populations. The TEFT initiative builds 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.

The TEFT grant program has four components. First, the TEFT states are testing the Experience of Care (EoC) survey for the Home and Community-Based Services (HCBS) population; second, the TEFT grants are being used to help states develop personal health records (PHR) for their waiver populations; third, TEFT states are participating in the development of an electronic Long-Term Services and Supports (eLTSS) standards and interoperability (S&I) framework with the Office of the National Coordinator for Health Information Technology (ONC); and fourth, the FASI component is building on these interoperability efforts and aligning functional measurement in HCBS programs with CMS' larger data standardization efforts.

This package requests approval from the Office of Management and Budget (OMB) for the FASI component which builds on the Continuity Assessment Record and Evaluation (CARE) items (Form CMS 10243; "OMB 0938-1037") as published in FR 72, No. 144 (July 27, 2007). FASI is based on a subset of the CARE items which are now included in Federal assessment forms for nursing facilities (MDS), inpatient rehabilitation facilities (IRF-PAI), and long term care hospitals (LTCH-CARE) to measure function in a standardized way. The proposed FASI items include the standardized mobility and self-care items included in the MDS, IRF-PAI, and, LTCH CARE 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 that were tested in the CARE item tests, and some modified caregiver assistance items currently included in the Federal 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. See the attached file (TEFT FASI Items) for the complete FASI set of items.

The purpose of the TEFT FASI initiative is to test the application of the standardized items' reliability and validity when used across home and community-based service (HCBS) populations. The targeted subpopulations for this project are:

- 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).

While many of the items have been tested with the aged and disabled populations in the Medicare program, they have not been tested for reliability with ID/DD populations or the severely mentally ill.

The results of the FASI initiative will provide 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 two Technical Expert Panels (TEP) that were 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 and the second TEP was held October 2015. The TEPs each 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); and
- 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).

The CARE items were developed by CMS and tested for reliability under the Post-Acute Care Payment Reform Demonstration (Gage et al., 2012). Since that time, CMS has been incorporating them in the development of standardized assessment items in the Federal assessment tools used in the inpatient rehabilitation facilities, long-term care hospitals, nursing facilities, and home health agencies as mandated by the IMPACT Act of 2014. The CARE items had been developed with extensive input from providers, consumer communities, and researchers in the field and are basis for the FASI function items being tested here. After being tested for reliability and validity in more than 200 provider settings nationwide, they were also tested in community-based and nursing facility-based populations receiving occupational, physical, or speech therapy services under the Medicare Part B benefit (Silver et al., 2013; Lyda-McDonald, Silver, and Gage, 2011).

The TEFT FASI project, the focus of this Paperwork Reduction Act (PRA) submission, builds on this previous work by reinstating the OMB authorization and adapting the existing CARE items as described above. The resulting HCBS FASI Item Set will be tested for reliability (including inter-rater reliability) and validity with each of the target subpopulations. Once reliability and validity have been established, the states involved in the FASI component of the TEFT project may voluntarily select items from the FASI Item Set to determine how they could be used for eligibility, level of care determination, person-specific care planning, or other state-determined uses such as monitoring access and quality of care. For example, the items may be combined, weighted, and scored for state- and program-specific eligibility determination (see *Figure 1*).

### **Figure 1. Eligibility criteria**

States set Medicaid eligibility criteria for their programs based on factors unique to their state, including the amount, duration, and scope of services a program offers. Additionally, states use eligibility criteria to manage utilization. For Medicaid programs, eligibility criteria are used to determine medical necessity, as required by federal law. States have considerable flexibility in setting these criteria, which has led to major variations in assessment instruments and practices across states. For example, virtually all states consider activities of daily living (ADL) impairments when determining eligibility, but one state may require a need for extensive assistance with three ADLs to be eligible and another only moderate assistance with two ADLs. The development of standardized ADL measures will enable data about these measures to be compared across states.

The FASI Item 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 its efforts to standardize their approach for measuring health and functional complexity, they have been developing an assessment item library which includes the standardized items found to be reliable across populations, including medical conditions, cognitive status, and other individual factors tested in the earlier OMB-approved CARE Item Set as well as other historical items. These efforts are useful for meeting the requirements of the IMPACT Act, which calls for standardized items to measure function and other factors across post-acute populations, and tracks the availability of reliable assessment items that can be used across programs.

The standardized function items being tested in the TEFT grants are a subset of those in the CMS data element library and are now included in the federal data collection forms, including the Minimum Data Set (MDS) used in nursing facilities. Use of the same items to measure functional status in nursing facilities and community-based programs will be helpful for states reporting 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 standardized items will be useful for states as they develop their personal health records and select items for use in the e-LTSS data exchangeability component of the TEFT grants. States also will benefit from having standardized functional status items to use in the following activities:

- Development of person-centered service plans
- Determination of eligibility for state programs
- Monitoring the quality and measuring the state program impact
- Reporting across multiple programs within a state, and across states, especially rebalancing initiatives
- Updating state systems to reflect national measurement standards
- Creating exchangeable data platforms

Once the items have been finalized and tested for reliability under the TEFT Round 1 data collection, Truven Health Analytics will be mapping the items to national Health Information Technology (HIT) exchange standards and using them to submit HCBS FASI measures for endorsement to the National Quality Forum (NQF).

## **A. JUSTIFICATION**

### **A.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 Item Set, developed through the TEFT project, directly supports CMS's implementation of the ACA regulation.

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. 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).

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, if found to be reliable in each of the HCBS populations, can 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.



## **A.2 Information Users**

This data collection effort amends the CARE data collection effort identified above. Individual-level data will be collected two times using the TEFT FASI Item Set. The first data collection effort will be conducted by Truven Health Analytics, working with the 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. Assessors will conduct functional assessments in client homes using the TEFT FASI Item Set. They will enter the data into an electronic PDF data collection tool developed by Truven Health Analytics. The data will be uploaded to Truven Health Analytics on a weekly basis using a secure electronic transfer file. Truven Health Analytics will send the de-identified field test data to the George Washington University for reliability and validity analysis. (See attached Data Security Plan.)

All data will be maintained in a secure environment at Truven Health Analytics and GWU, and access will be limited to analysts working on this project. Personally identifiable information (PII), such as last name, first name, mailing address, and contact information will be used by the states and the data collectors to identify the sample and enroll participants. These data will be protected by Truven Health Analytics using approved data security methods. These identifying items will be stripped before the data are transferred to GW for analysis. No PII data will be required for analysis since the data will not be linked to claims or any other data sources. Data will be 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.

The results of the reliability and validity testing will be provided to CMS in a FASI Field Test Report. The report will include 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 may recommend changes to individual TEFT FASI items, to be made prior to releasing the TEFT FASI items for use by the states. Once all of these actions have occurred, and pending approval from CMS, the FASI Field Test Report will be released to the public.

The second data collection will be conducted by the states to demonstrate their use of the FASI data elements. The assessment data could be used by the states for multiple purposes. They may use the standardized items to determine individual eligibility for state programs, or to help determine levels of care within which people can receive services, or other purposes. Truven Health Analytics will be providing technical assistance to the TEFT states to help them consider how each state will use the standardized data. In the second round of data collection, states will demonstrate their proposed uses, manage their FASI data collection and conduct their own analysis, to the extent they propose to do such tasks. The states have been funded under the demonstration grant to conduct the round 2 data collection and analysis. These states will submit reports to CMS describing their experience in the Round 2 data collection, including the items they collected, how they planned to use the data, and the types of challenges and successes they encountered in doing so. The reports may be used by CMS in their evaluation of the TEFT grants.

## **A.3 Use of Information Technology**

This PRA submission addresses data collection that will allow Truven Health Analytics to test the validity and reliability (i.e., field test) of the standardized items that comprise the TEFT FASI Item Set. Round 1 response to questions in the TEFT FASI Item Set will be

collected by assessors using an electronic PDF form to collect the data. They will use their professional laptops on which they currently collect assessment data. The data will be uploaded to Truven Health Analytics using a secure file transfer protocol and will be maintained in a secure application as described in the security plan.

The Truven Health Analytics data storage secure application is being developed only to support the TEFT FASI field test and other components of the CMS TEFT grant. Because this is a field test, signatures of consumers being assessed (respondents) and assessors will not be collected by Truven Health Analytics. Individual assessors will be collecting signed consent documentation from their clients and maintaining the information in their locked offices where they hold other PII data. All respondents will be given consent forms to ensure the test meets the requirements of the George Washington University and other states' Institutional Review Boards (IRB) for this type of data collection.

#### **A.4 Duplication of Efforts**

Field test data collection 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 TEFT FASI items tested in this project are designed to standardize the data collected across settings, populations, programs, and states. Though states may continue to collect data using their current assessments during this testing phase, the TEFT FASI items may eventually replace their current items should they choose to incorporate TEFT FASI items into their universal/uniform assessment tools. There is no requirement for the states to use TEFT FASI items beyond this demonstration project.

All state Medicaid programs collect similar data on many of the domains of the TEFT FASI Item Set. However, the items states use generally have not been tested for reliability and validity; often vary across target populations, states, and programs within states; and are not compatible with the Federal standardized items collected in nursing facilities and home health agencies, as well as other post-acute care (PAC) settings. Thus, they cannot be used across settings, populations, programs, or states to track changes in the status of beneficiaries or to assess the quality of providers or programs. Existing CARE items have been tested for reliability and validity in PAC settings, but have not been tested previously in the Medicaid HCBS context. These items may not all be deemed appropriate or valid for the HCBS population, thus providing the justification for the TEFT FASI project. In addition, the new items developed in this project have not, to our knowledge, ever been tested for reliability and validity, even though the domains are widely used in state assessment instruments.

#### **A.5 Small Businesses**

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

#### **A.6 Less Frequent Collection**

This data collection is proposed to be used in the TEFT round 1 data collection to test the reliability and validity of the FASI data items as described above. States may choose to use a

subset of the tested FASI data items in the round 2 data collection in 2017 as a component of their TEFT demonstration efforts. Data collection will be limited to individuals within the six states that have selected the FASI component of the TEFT project. Should we discover that there is insufficient sample size to field test the TEFT FASI data items for a subpopulation, we are required to recruit other states or organizations that can potentially contribute clients in that subpopulation to achieve the necessary sample size.

The information collected in this study will provide CMS with essential information to determine whether and which assessment items should be added to CMS's library of data elements and 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 will fill an information gap, and will enable policymakers to make informed decisions about Medicaid LTSS programs, eligibility, services, and costs moving forward.

## **A.7 Special Circumstances**

This collection is not connected with a statistical survey that is not designed to produce valid and reliable 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.

## **A.8 Federal Register/Outside Consultation**

### **A.8.1 60-day Federal Register Notice**

The 60-day notice published in the Federal Register on May 2, 2016 (81 FR 26235). One comment was received and is attached to this package along with our response.

Following publication in the Federal Register on May 2, 2016, we have made several minor modifications to the form that further protect participant identification or improve the response efficiency by removing several checkboxes we were using for item screening purposes. The instructions were revised accordingly. These are based on internal decisions and have not resulted in revised burden estimates.

The changes to the form include the following:

- Added an assessor certification statement to document their compliance with privacy protections
- Section A: Removed items on age, gender, and waiver population
- Section B: Removed checkbox at the start of each subsection that identified “no changes during the past month” and revised instructions to complete both columns. For those using the electronic PDF, the 30 day column will

automatically prefill to note no change from the past 3 days. This is intended to reduce the respondent burden.

- Section C: Added a checkbox to denote that the assessor has indicated all the devices needed.
- Section D: Revised the instruction to clarify the use of “not applicable.”

### **A.8.2 Efforts to Consult Outside Agency**

CMS authorized two 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.

The members of the first TEP and their affiliation, areas of expertise, and contact information are listed in **Table 1**.

**Table 1**  
**Technical expert panel members**

Name	Affiliation	Expertise
Bernstein, Amy, MMHS	Director, Community Based Waivers, MassHealth, Boston, MA	Over 20 years of experience in a variety of policy and operational positions related to CB-LTSS. She is currently responsible for the administration/oversight of the state's 10 HCBS Waivers.
Bershadsky, Julie, PhD	Senior Research Associate, Human Services Research Institute, Cambridge, MA	Project Director of the National Core Indicators – Aging and Disabilities (NCI-AD), which is an expansion of the National Cancer Institute (NCI) to the population of aging adults, and adults with disabilities receiving LTSS.
Brent, Barbara, MS	Director of State Policy, National Association of State Directors of Developmental Disabilities Services (NASDDDS), Phoenix, Arizona and Alexandria, Virginia	Provides analysis of national and state policies. Areas of special focus include health care reform, Medicaid authorities, managed care long-term services and supports, acute health care, and transition from facilities into robust community-based service delivery systems.
Elliot, Mary-Jo, RN	Clinical Manager, Personal Care Attendant Program, MassHealth, Office of Long-Term Services and Supports, Boston, MA	Extensive knowledge of long-term care and Medicaid/Medicare regulations including policy, funding sources, community services, recording keeping, and compliance.
Erkel, Pam	Manager, Special Projects Disability Services Division, Department of Human Services, State of Minnesota, St. Paul, MN	Designs and shapes home care and case management reform projects that will help create a more sustainable LTSS system in Minnesota.
Harley, Linda, PhD	Research Scientist, Georgia Tech Research Institute (GTRI), Atlanta, GA	Experienced in the in-home assessment of elders, and in understanding the interplay of person, adaptive equipment, and environment to support health and independence.
Holt, Kathleen, MBA, JD	Associate Director, the Center for Medicare Advocacy, Waterford, CT	Developed Washington state assessment program including in-home and community-based services; worked with CIGNA to build a claims payment system; 20 years' experience as attorney advocate for disabled.
Lebsock, Jakenna, MPA	Quality Improvement Manager, Arizona Health Care Cost Containment System (AHCCCS), Phoenix, AZ	Quality improvement manager of AHCCCS. Arizona is one of the TEFT grantee states.
Leitch, Kathy, MSW	Principal, Health Management Associates; formerly Assistant Secretary, Aging and Disability Services Administration, Washington State Department of Social and Health Services, Olympia, WA	Extensive experience with the design and operations of LTSS systems serving older people, people with physical disabilities and persons with ID/DDs.
Lerza, Cathy, BA	Quality Assurance Manager, Commonwealth of Kentucky, Division of Developmental & Intellectual Disabilities, Frankfort, KY	Involved in the development of Kentucky's Medicaid Waiver Case Management system. Helped write two of Kentucky's HCBS waivers.
Levelle, Jeanne, RN	Office of Aging and Adult Services, Department of Health and Hospitals, State of Louisiana, Baton Rouge, LA	The Office of Aging and Adult Services aims to develop, provide, and enhance services that offer meaningful choices for people in need of long-term care.

Name	Affiliation	Expertise
Lulinski, Amie, PhD	Director, Rights Policy, The Arc of the US, Washington, DC	Worked with and for individuals who have ID/DD and their families for over two decades. Represents The Arc on the Long-Term Services and Supports Task Force of the Consortium for Citizens with Disabilities.
Maslow, Katie, MSW	Scholar-in-Residence, The Institute of Medicine, Washington, DC	Care-related issues for older people with dementia, mental illness and coexisting medical conditions.
O'Malley, Terrence, MD	General Internist and Geriatrician, Massachusetts General Hospital, and Partners HealthCare System, Inc., Boston, MA	Extensive experience with HCB LTSS including work with the Aging Services Access Points. Familiar with the range of services needed to maintain individuals at home and in their highest level of function.
Orlowski, Gwen, JD	Senior Staff Attorney, National Senior Citizens Law Center, Washington, DC	Leading advocate on long-term care issues affecting older individuals and adults with disabilities.
Ross, Clarke, DPA	Public Policy Director, American Association on Health and Disability, Crofton, MD	Disability expertise in community-based LTSS, public policy, and the measurement of performance, outcomes, and quality.
Royall, Donald, R., Jr., MD	Tenured Professor and Chief of the Division of Aging and Geriatric Psychiatry at the University of Texas Health Science Center at San Antonio (UTHSCSA)	Primarily interested in the cognitive correlates of functional status, executive function, the Default Mode Network (DMN), and their importance to dementia case-finding.
Saliba, Debra, MD, MPH	Director, UCLA/JH Borun Center for Gerontological Research and adjunct staff at the RAND Corporation	20 years of experience in conducting research that addresses quality of care and assessment of vulnerable older adults across care settings including community settings, clinics, hospital, home and nursing home.
Shugarman, Lisa, PhD	Consultant, Former Director of Policy, The SCAN Foundation, Long Beach, CA	Nationally recognized expert in aging, LTSS, Medicare, Medicaid, and dual eligibles policy and research.

The TEP met for a 2-hour conference call on September 12, 2014. Prior to the call, the TEP was provided with extensive materials to review in advance, including:

- Overview of the TEFT project;
- Overview of the TEFT FASI project;
- Overview of past CARE initiatives; origins of the existing CARE Item Set;
- Decision rules for adapting existing CARE items for the HCBS population, resulting in the TEFT FASI Item Set;
- The list of unmodified CARE items;
- The list of modified CARE items;
- The list of newly developed TEFT FASI items;
- The list of excluded CARE items;
- Agenda for the September 12, 2014 meeting; and
- Goals, objectives, roles, and responsibilities of the TEP.

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 Item 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.

TEP feedback during meetings was documented in the minutes. Additional written feedback provided in advance of the meeting was solicited from TEP members via email before the meeting. In addition, they were requested to provide written feedback to the revised materials after the meeting. All TEP members had the opportunity to review and revise their feedback before it was considered final. TEP members received a \$750 honorarium for their participation.

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.

The TEP was held by phone and included the experts identified in Table 2. Many of the experts work with at least one of the target populations or have expertise in measurement or data collection among these populations. All TEP members, except those representing a state agency, were paid a \$500 honorarium for their participation.



**Table 2**  
**TEP Participants for 2015**

<b>Name</b>	<b>Affiliation</b>
Marcus Canaday	Money Follows the Person Program, West Virginia
Camille Dobson	National Association for State Units on Aging and Disability
Sarah Ekart	Georgia, TEFT Grantee
Pam Erkel	Minnesota, TEFT Grantee
Nancy Flinn	Courage Kenny Rehabilitation Institute
Tamar Heller	University of Illinois at Chicago, University Center of Excellence in Developmental Disabilities For the State of Illinois
Kathleen Holt	Center for Medicare Advocacy
Alan Jette	Institute of Medicine Disability Committee, Boston University, Health and Disability Research Institute
Karen Kimsey	Complex Care and Services, Virginia
Jakenna Lebsock	Arizona, TEFT Grantee
Cathy Lerza	Kentucky, TEFT Grantee
Jeanne LeVelle	Office of Aging and Adult Services, Louisiana
Katie Maslow	Institute of Medicine
Terrence O'Malley	Mass General Hospital, Partners Health, Boston
Sherry Ostrout	Connecticut Community Care Inc.
Julie Robison	Connecticut, TEFT Grantee
Deb Saliba	University of California, Los Angeles, Veterans Affairs, RAND
Ken Slavin	Therapy Services
Mary Sowers	National Association of State Directors of Development Disability Services
Marilyn Spivack*	Neuro-trauma Outreach Coordinator, Advocate, Spaulding Rehabilitation Hospital, Boston
Kelly Wilson	Colorado, TEFT Grantee

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

## **A.9 Payments/Gifts to Respondents**

Truven Health Analytics will not be paying respondents to participate in the TEFT FASI data collection.

## **A.10 Confidentiality**

Truven Health Analytics, GWU, and CMS will keep all FASI field test data confidential. Only authorized staff at CMS and the Truven 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.

Individuals and organizations contacted will be further assured of the confidentiality of their replies under 42 U.S.C. 1306, and 20 CFR 401 and 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.

## **A.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 TEFT FASI assessment. The purpose of the FASI assessment items 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.

In this test phase, information from these sensitive questions will be used to assess the reliability and validity of the items. In the implementation phase, state Medicaid HCBS programs may use 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.

## **A.12 Burden Estimates (Hours & Wages)**

The burden response estimates for the Round 1 data collection conducted by Truven are shown in **Table 3** (hours) and **Table 4** (costs). Assuming the same level of collection during Round 2, **Table 5** (hours) and **Table 6** (costs) show the potential burden response estimates for

the state in Round 2. While we have included Round 2 data collection burden estimates, states have not yet determined the size of their Round 2 effort, including the number of items or the number of respondents so these are estimates based on the best information we have available at this time. These estimates are not affected by the minimal revisions in the 30 day package.

**Round 1**

Under the Round 1 data collection managed by Truven, we expect 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 1570 (5 x 314).

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 3**  
**Estimated annualized burden hours**

Section name	Number of respondents	Average Number of minutes per respondent	Median Minutes per respondent	Total burden hours
Section A: Person Demographics	1570	4	5	130.83
Section B1: Self Care	1570	5	5	130.83
Section B2: Mobility	1570	6	5	130.83
Section B3: IADLs	1570	5	5	130.83
Section C: Assistive Devices	1570	4	5	130.83
Section D: Support / Caregiving	1570	4	5	130.83
All sections	1570	28	30	785

Source: Truven Health Analytics estimates based on pilot study.

**Table 4**  
**Estimated annualized cost burden**

Section name	Number of respondents	Total burden hours	Median \$/ hour wage rate	Total cost burden, \$
All sections	1570	785	\$25	\$19,625
Total	1570	785	\$25	\$19,625

Source: Truven Health Analytics 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 Tables 3 and 5, the estimated seasonally adjusted hourly earnings for all employees on private nonfarm payrolls in May 2014 was \$25/hour (U.S. Bureau of Labor Statistics, 2014). Thus, the total estimated burden cost will be \$19,625 assuming 1,570 completed assessments. An estimate of \$25 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.

## Round 2

States will use the findings from the Round 1 data collection to finalize their plans for their demonstration efforts or Round 2 data collection. Since the Round 2 effort is state-specific, we have little basis to quantify any burden estimates since we do not know the states’ collection methodology, the number of respondents within each state, the questions each state will ask- if any - and the number of questions asked, etc. Consequently, we are setting out state Round 2 data collection burden as a potential range of estimates, including an assumption that all beneficiaries in each state program will be included and that they will test all the items, although this level of testing is the highest potential burden and is not expected; the actual burden will be less than this amount. While states need to report their findings to CMS, we are not setting out such burden since the reporting requirement applies only to 6 states. This is below the PRA threshold of 10 or more (5 CFR 1320.3(c)) “persons.”

**Table 5**  
**Estimated annualized burden hours**

Section name	Potential Number of respondents	Average Number of minutes per respondent	Median Minutes per respondent	Total burden hours
Section A: Person Demographics	.	4	5	.

Section B1: Self Care	.	5	5	.
Section B2: Mobility	.	6	5	.
Section B3: IADLs	.	5	5	.
Section C: Assistive Devices	.	4	5	.
Section D: Support / Caregiving	.	4	5	.
All Sections	.	28	30	.
By State (# of resp * 30 min)	.	.	.	.
Arizona	581	.	30	290.5
Colorado	1102	.	30	551.0
Connecticut	567	.	30	283.5
Georgia	448	.	30	224.0
Kentucky	478	.	30	239.0
Minnesota	904	.	30	452.0

Source: Truven Health Analytics estimates based on TEFT Experience of Care Survey Sample.

**Table 6.**  
**Estimated annualized cost burden**

Section name	Number of respondents	Total burden hours	Median \$/ hour wage rate	Total cost burden, \$
All sections	4080	2040	\$25	\$51,000
Total	4080	2040	\$25	\$51,000

Source: Truven Health Analytics estimates.

### A.13 Capital Costs

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

### A.14 Cost to Federal Government

Costs to the federal government include the costs for the item development, Technical Expert panels, cognitive testing and field testing. Field testing costs include the cost of developing the data collection tools, the electronic portal, contracting with and training local assessors to collect the data, and storing the data in a secure environment at Truven Health Analytics. Total costs for Round 1 data collection include \$949,625 for the RTI contract for the first TEP; \$1,002,740 for the Truven team, including the subcontractors at George Washington University for the costs of the second TEP, conducting the alpha test, developing the electronic training modules, providing helpdesk services, and managing the data collection. In addition, an estimated \$691,836 cost will be incurred to hire the local assessors in all six states as well as \$188,785 that was paid to the states for their costs incurred in the Round 1 data collection. The TEFT grants also provide an additional \$1,694,101 to states for their Round 2 data collection.

Costs to the Federal government include a total of \$4,527,807 over four years or \$1,131,951.75 annually. These costs include the following:

Year 1	Item Development: RTI - \$949,625
Year 1	Technical Assistance on Item Development : Truven - \$34,599
Option Year 1:	Item Development/Refinement, TEP, Alpha Testing: Truven and subcontractors - \$1,002,740
Option Year 2:	State collecting Round 2 data: \$1,694,101

These costs provide funding for consensus development of the items, field testing them to examine their psychometric properties, and then implementation by the states in their respective program management efforts.

### **A.15 Program and Burden Changes**

This is a request to use the reinstated CARE tool authorization. The PAC CARE was established in 2007 for use in the Post-Acute Care Payment Reform Demonstration. Some of the items have since been incorporated into the Federal assessment tools required in the nursing facilities (e.g., the Minimum Data Set (MDS), and other related assessment tools used in Medicare payment and quality reporting requirements related to post-acute care services. The TEFT demonstration would like to use the reinstated authorization so that the adapted CARE items in the FASI can be tested for reliability and validity in the community-based long term services and supports (CB-LTSS) populations. The data burden for the FASI items is much smaller than the earlier CARE item set as the average time to complete each section is five minutes and the total burden estimate for the complete set of FASI items is 28 minutes. The title of the package is also being changed to reflect that the FASI item set is only a subset of the original CARE items. The new title reflects this while also referring back to the source items in the CARE tool.

## **A.16 Publication/Tabulation Dates**

### **Field Test Dates**

Truven Health Analytics will collect data during a 6 month field test beginning immediately after OMB authorization. The field test data collection will begin June 2016, assuming authorization has been given.

### **Data Analysis Dates**

Data review will begin almost immediately following data submission. Truven Health Analytics will conduct weekly checks on the data that have been submitted to ensure it is being collected correctly. The data will be analyzed over the following 12 months and used to prepare reports to CMS on the results. Final analysis of the reliability of the items will be completed for presentation to a Technical Expert Panel (TEP) in March of 2017. Comments will be incorporated into a final report on the Round 1 data collection and submitted during 2017. States will use the findings from the Round 1 data collection to finalize their plans for their demonstration efforts or Round 2 data collection.

### **A.17 Expiration Date**

The OMB expiration date will be displayed on all disseminated data collection materials.

### **A.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.

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