New Jersey 1115 Demonstration Interim Report

New Jersey FamilyCare Comprehensive Demonstration Annual Report Demonstration Year: 13 (July 1, 2023 – June 30, 2024) Reporting Quarter: #4 (April 1- June 30, 2024)

Executive Summary

I. 1115 DEMONSTRATION OVERVIEW

On March 30, 2023, CMS approved New Jersey's request to extend and amend its New Jersey FamilyCare Comprehensive Demonstration from April 1, 2023 through June 30, 2028. The FamilyCare Demonstration seeks to expand longstanding waiver and expenditure authorities that make up a crucial part of New Jersey's Medicaid system, including 1) the extension of managed care to include long-term services and supports (LTSS) and certain behavioral health services; 2) targeted home and community-based services (HCBS) programs for children; 3) support services and in-home community supports for individuals with intellectual and development disabilities (I/DDs); 4) expenditures for substance use disorder (SUD) services; 5) continuation of eligibility determinations for individuals placed under the guardianship of the Office of the Public Guardian (OPG); and 6) extension of full state plan benefits to postpartum individuals enrolled in Medicaid or CHIP for up to 12 months from the last day of an individual's pregnancy.

The approved Demonstration extends these authorities, among others, and allows the state to test the efficacy of innovative practices that seek to promote high-quality, evidence-based, coordinated, and integrated care. Through new initiatives and investments, New Jersey also hopes to improve coverage, access, quality of services, and health equity for Medicaid and CHIP beneficiaries. The Demonstration's ultimate goal is to enhance medical assistance and improve health across New Jersey, leading to additional populations served and services provided under Medicaid.

II. QUARTER ACCOMPLISHMENTS, ACTIVITIES, AND MILESTONES

Over the course of Demonstration Year 13, New Jersey began the process of planning and implementation on several of the new 1115 initiatives approved as a part of the renewed demonstration. During DY13, DMAHS staff collaborated with various stakeholders across the state to start planning the implementation of the new initiatives, including Behavioral Health Integration, HRSN services and Housing Benefit. During this year, the Behavioral Health Promoting Interoperability Program was launched. Additionally, the extension of the Respite benefit from 31 to 90 days was launched during this year and services have begun to be authorized and delivered by the MCOs. Additionally, DMAHS held a Post Award Forum to solicit comments from various stakeholders such as MCOs, CBOs, Provider Organizations and Members on the upcoming Demonstration programs.

During the fourth quarter, multiple implementation activities continued. In anticipation of the integration of some behavioral health services into managed care as a part of Phase 1 of the Behavioral

Health Integration, DMAHS added language into the July MCO Contract to strengthen requirements for MCOs and ensure streamlined and coordinated care. The MLTSS team met with the MCOs to discuss potential barriers which must be solved prior to implementation and necessary systems changes. The HRSN team submitted the HRSN Infrastructure protocol to CMS which was approved on April 18th.

New Initiatives Implementation Updates

I. SUMMARY AND ANALYSIS OF IMPLEMENTATION ACTIVITIES FOR NEW INITIATIVES

1) Behavioral Health Integration Program

The State submitted the July MCO contract to CMS. In anticipation of Phase 1 of the integration of some behavioral health services into managed care in January 2025, DMAHS significantly strengthened behavioral health requirements for MCOs. An amendment to ensure access and continuity of care for members including requiring MCOs to cover court-ordered behavioral health services was added to the contract language. Another amendment to enable streamlined, coordinated care delivery which includes changes to prior authorization requirements and mandating MCOs to employ a full time, in-state Behavioral Health Medical Director was added.

Additionally, the bi-monthly Advisory Hub meeting was held on April 25 with various stakeholders from other government agencies, MCOs, CBOs, Provider organizations, Hospitals and others. During the meeting, Advisory Hub participants delivered feedback on two topics: MCO integrated care management and quality monitoring.

2) Continuous Eligibility

DMAHS continues to explore the expansion of continuous eligibility under the Demonstration but has not come to a conclusion. Future updates will be included if and when DMAHS determines the expansion should be undertaken.

3) Managed Long-Term Services & Supports (MLTSS)

a) Caregiver Supports: Respite

The Respite benefit extension was successfully implemented and expanded from 31 to 90 days per calendar year. The definition for the service was changed and became effective on January 1, 2024. The MCOs continue to authorize and deliver the service accordingly.

b) Caregiver Supports: Therapy

DMAHS continued ongoing work on program design including provider payment, monitoring and oversight requirements, and a plan for stakeholder engagement. Several design sessions were held both internally and with other states. Based on feedback from MCOs, the state has encountered issues regarding systems changes needed to ensure compliance with privacy regulations, processing claims, ensuring legitimate caregivers to avoid fraudulent billing, and maintaining authorizations for services that will be delivered to a person who is not enrolled in Medicaid.

The MCOs expressed concern that systems changes required to resolve these issues would not be cost effective and would require a lot of time to accomplish. Through discussion with other states, DMAHS determined services could be provided to the caregiver under the members Medicaid ID rather than using a unique identifier or issuing another form of ID for caregivers. Initial MCO feedback was that neither their provider portals nor their care management systems are configured to process claims for caregivers who are not Medicaid members. DMAHS continues exploring options, including use of a HIPAA compliant vendor tool. DMAHS is also exploring the potential of working in partnership with our Division of Aging Services as they work to procure a platform to develop and host a caregiver hub.

4) Behavioral Health Promoting Interoperability Program (BH PIP)

On May 1st, 2024, at a New Jersey Association of Mental Health and Addiction Agencies (NJAMHAA)IT conference, the BH PIP was officially announced. The presentation outlined the program milestones, the implementation timeline and included a Q&A session for the attendees. Additionally, a revision to the "Telehealth" milestone payment, previously approved in the Implementation Protocol was submitted for CMS approval. The state recognizes the need to align the telehealth milestone payment for the BH PIP with the state funded Substance Use Disorder Promoting Interoperability Program (SUD PIP) and is awaiting CMS's decision on the proposed change.

5) Quality Improvement Strategy

During this reporting period (DY13), DMAHS agreed to participate in an HCBS Quality Improvement Strategy (QIS) pilot offered by CMS in light of the Access and Managed Care Final rules. This pilot serves as a vehicle to assist NJ in complying with the new HCBS reporting requirements in the final rules. In November 2023, CMS and DMAHS started meeting on a regular monthly cadence to develop a new template for performance measures for NJ's HCBS populations within the demonstration using the HCBS Measure Set. As a result of the pilot, DMAHS began working closely with our sister agencies to review draft proposed HCBS performance measures/activities, survey which populations would be measured, and additionally, decide how we would address the HCBS child population. NJ in partnership with CMS continues to make progress towards a finalized template. During Q4, CMS sent DMAHS a revised draft of the performance measures template for the HCBS pilot. In follow-up, DMAHS sent CMS technical questions in response to the revised draft. While waiting for feedback from CMS, DMAHS continued to review feasibility of reporting specific measures proposed in the template with sister agencies. During our review, CSOC identified that there was no experience of care (EOC) survey applicable to NJ's child HCBS population. CMS agreed to identify an EOC survey applicable to the child HCBS population for inclusion in the pilot.

6) CSSP Program Expansion

During this quarter, CSOC continued to work on operationalizing the steps necessary to provide Plan A to eligible I/DD populations. This included planning for the initial Phase 1 rollout which was anticipated to begin in the fall of 2024. CSOC worked on developing manual entry forms such as (enrollment/disenrollment/change) to assist Intuitional Support Services (ISS) in managing the newly identified waiver participants

7) Health-Related Social Needs (HRSN)

a. Housing Supports

After receiving approval of the infrastructure protocol in April, DMAHS pivoted to identify how funds would be distributed to stakeholders. Ultimately, DMAHS decided to partner with the NJ Department of Community Affairs (DCA) Office of Homelessness Prevention (OHP). DCA is the state's primary housing agency. Work continued over the next several months formalizing the partnership and building out the grant program. DMAHS submitted the HRSN Services Protocol to CMS in May 2024. To ensure MCOs were prepared to operate the program, DMAHS set up a reoccurring meeting cadence with the MCOs to help inform and drive program design, which include 1:1 meetings, all MCO meetings, and issue specific working meetings. DMAHS also expanded its relationship with the Regional Health Hubs (RHHs). The RHHs will perform a variety of functions including developing and hosting statewide trainings, helping standardize materials and processes, as well as providing TA to housing organizations. Program design focused on identifying and designing the necessary IT and systems infrastructure, provider enrollment, developing the payment rate structure for all the services, and building out the service authorization process.

b. Nutrition Supports

Design work for these benefits continues with internal and external stakeholder meetings. The target date to launch the service is July 2025 to align with the start of the state fiscal year and the start of the MCO contract cycle. In preparation to launch these benefits, DMAHS will monitor MCO establishment of network providers, finalization of procedure codes, finalization of eligibility criteria based on CMS feedback, finalization of a uniform assessment tool to accurately capture eligible members, development of provider guidance and member outreach and engagement.

c. Medically-Indicated Meals (MIM)

DMAHS set up informational meetings with MCOs to share design updates and gauge interest in participating in the MIM pilot. DMAHS asked any interested MCOs to respond by April 30, 2024. Several MCOs expressed interest and participated in meet and greet sessions organized by DMAHS with potential meal vendors. The MIM team in partnership with other HRSN implementation teams completed a draft of 1115 HRSN Services Protocol ahead of submission to CMS in May 2024. Development of program design continued with a focus on determining service elements for inclusion in the pilot, exploring the payment rate structure, and building out the service authorization process.

Ongoing Initiative-Specific Reporting

I. SUMMARY AND ANALYSIS OF IMPLEMENTATION ACTIVITIES FOR ONGOING INITIATIVES

A. MANAGED LONG-TERM SERVICES & SUPPORTS (MLTSS)

A new MLTSS Director began at DMAHS with the previous MLTSS director remaining connected to day-to-day operations and implementation of new nutritional support and caregiver counseling services. DMAHS continued working with contracted and MLTSS partners to redefine MLTSS goals and performance measures, develop an HCBS data dashboard, improve the overall MLTSS data structure and redesign a reinvigorated operating model. Regular weekly discussions and meetings were held with leadership and staff to develop an agreed upon target state operating model. Once defined, the MLTSS unit moved on to implementation measures to train staff, make organizational changes, change monitoring processes and oversight. DMAHS then began defining MLTSS teams, referred to as squads, tasked with focusing on three distinct aspects of the member experience beginning with eligibility and enrollment, through care management and coordination of care, to service delivery and quality assurance. Squads, which included representation from all MLTSS staff, were formed. The MLTSS director participated in monthly interagency meetings to plan for review and response to CMS' request for heightened scrutiny review of specific facilities. Regular meetings were held with MCOs and MFP partners.

EQR PIP UPDATE:

Recent Performance Improvement Plan (PIP) activity includes the following history and related progress:

A new PIP Topic was introduced to the MCOs in June of 2021. All 5 MCOs have submitted new PIP Proposals on the topic of "Improving Coordination of Care and Ambulatory Follow-up after Mental Health Hospitalization in the MLTSS Home and Community Based Services (HCBS) Populations (FUH)" in September 2021. The new PIP Proposals were accepted by the State in conjunction with the EQRO and feedback was provided to the MCOs in November 2021. All 5 MCOs submitted Year 1 Findings. Year 1 Findings were reviewed by the State and reviewed and scored by the EQRO in August 2022. Year 2 updates were received by the EQRO from the MCOs in April of 2023 and were reviewed by the EQRO and DMAHS. Year 2 Findings of the current FUH PIP were received and reviewed by DMAHS and the EQRO in August of 2023. Additionally, DMAHS then received the EQRO's feedback and scores calculated by the EQRO in September of 2023. DMAHS then reviewed the EQRO's findings and provided feedback for the August PIP submissions and EQRO findings to the EQRO. In October of 2023, DMAHS approved the August PIP submissions, along with the EQRO findings and the EQRO provided Year 2 Findings to the MCOs. DMAHS anticipates the upcoming submission of the April FUH PIP update from the MCOs to the EQRO followed by DMAHS review. DMAHS received the April FUH PIP submissions from the EQRO as anticipated. The April FUH PIP Sustainability update was received by the EQRO from the MCOs and were reviewed by the EQRO and DMAHS. The April FUH PIP Sustainability update was finalized and returned to the MCOs in June of 2024. DMAHS anticipates the EQRO findings for the August FUH PIP submission for the Sustainability year leading to the Final FUH PIP report

in August 2025. DMAHS plans to introduce PIP Topic "10 Day Post Discharge Follow-up with Assessment" to the MCOs in July of 2024 following the Annual PIP Training. DMAHS anticipates all 5 MCOs to submit PIP Proposals on the new MLTSS PIP Topic in October of 2024.

B. COMMUNITY CARE PROGRAM (CCP) AND SUPPORTS PROGRAM

During this quarter, DDD continued the implementation of Electronic Visit Verification (EVV) for the Community Care and Supports Programs. DDD reported that Phase 1 EVV compliance was at 69% and Phase 2 services increased to an 80% compliance rate. Quality audits and helpdesk responses continued. May 2024 was the submission deadline for the Development of Homes for People with Intellectual and/or Developmental Disabilities Transitioning from Nursing Facilities and other Qualified Institutions program. A committee will review the submissions. This program will provide community-based mobile crisis prevention and intervention services for people with I/DD with co-occurring mental health needs that are enrolled with DDD. This service is expected to reduce emergency use and hospital admissions, strengthen linkages with community partners to enhance support systems and increase resources, and to increase satisfaction of providers, individuals, and families. April 2024 was the submission deadline for the START model RFP. The program aims to provide community-based, mobile crisis prevention and intervention services for people with intellectual and developmental disabilities (IDD) and co-occurring mental health needs (MH) who are enrolled with and referred by DDD. A committee will review the submissions for the program.

C. CHILDREN'S SUPPORT SERVICES PROGRAM (CSSP) I/DD AND SED

During Q4 of DY13, CSOC focused on system requirements that included developing IT solutions that would be required to implement the demonstration. CSOC drafted forms, notices, and communications to support the implementation and provided necessary information for our partners, youth, and families. Preliminary training materials were created for staff that would be working with families to enroll youth into the Medicaid expansion through the demonstration. Youth continued to receive clinically appropriate services. There were no operational, administrative, fiscal, or legislative changes that impacted CSSP. During this quarter, 7,772 CSSP SED youth and 486 CSSP I/DD youth were actively enrolled.

Other Updates

I. DATA INFRASTRUCTURE AND HEALTH INFORMATION TECHNOLOGY

DATA INFRASTRUCTURE AND HEALTH INFORMATION TECHNOLOGY UPDATE:

The State successfully rolled out two additional milestones for the SUD PIP: eCMS and Telehealth. To support this implementation, a webinar was conducted to educate the facilities on these new milestones and to announce the launch of BH PIP, with the attestation period beginning July 1, 2024. During this quarter, one facility successfully implemented their EHR platform this quarter. One facility successfully integrated with the New Jersey Prescription monitoring Program (NJPMP) and enhanced their clinical workflow supporting safer prescribing practices. Additionally, three facilities completed the Telehealth milestones. As of quarter ending June 2024, a total of 2,560 licensed providers are actively engaged in the programs.

II. DEMONSTRATION EVALUATION

The State is testing the following hypotheses in its evaluation of the demonstration:

А.	Expanding Medicaid managed care to include long-term care services and supports will result
	in improved access to care and quality of care and reduced costs, and allow more individuals
	to live in their communities instead of institutions.
	The evaluator continued to monitor developments related to the Managed Long-term Services
	and Supports program and Medicaid overall through attendance at the Medical Assistance
	Advisory Council meeting on April 18, 2024. The evaluator worked on updating the MLTSS cost-
	effectiveness analysis for the summative report by examining a matched comparison group.
В.	Providing home and community-based services to Medicaid and CHIP beneficiaries and others
	with serious emotional disturbance, opioid addiction, pervasive developmental disabilities, or
	intellectual disabilities/developmental disabilities will lead to better care outcomes.
	During this quarter, the state's independent evaluator worked on summative report analyses
	using information provided by CSOC last quarter and by DMAHS and CSOC in this quarter.
С.	Utilizing a projected spend-down provision and eliminating the look back period at time of
	application for transfer of assets for applicants or beneficiaries seeking long term services and
	supports whose income is at or below 100% of the FPL will simplify Medicaid eligibility and
	enrollment processes without compromising program integrity.
	The State's independent evaluator continued communication with DMAHS regarding interpreting
	data and obtaining new data that will be used in the summative report to address this
	hypothesis.
D.	The managed care expansion will improve access to care, the quality, efficiency, and
	coordination of care, and the cost of care for the overall population in managed care.
	The state's independent evaluator utilized HEDIS and CAHPS previously provided by DMAHS to
	continue drafting materials for the summative evaluation.
Е.	Mandating individuals who have access to employee sponsored insurance into the premium assistance program will cost the State at least 5% less than providing individuals coverage in NJFC
	The state's independent evaluator continued to draft materials for the summative evaluation.
F.	Other hypotheses to address new research questions in the Demonstration renewal:
	 What is the impact of providing home and community-based services to
	expanded eligibility groups, who would otherwise have not been eligible for
	Medicaid or CHIP absent the demonstration?
	What is the impact of providing substance use disorder services to Medicaid beneficiaries?
	Including paying for services rendered in an institution for mental disease (IMD)?
	<u>OUD/SUD</u> : During this quarter, the State's independent evaluator communicated via email with
	State subject matter experts to discuss material for the summative evaluation report regarding
	administrative costs.
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G.	Evaluation of CHIP continuous enrollment – Hypothesis: Extending continuous coverage for
	CHIP children from March 2020 through June 2024 will result in greater coverage and higher

quality of care among eligible beneficiaries during the study period of January 2020 through December 2023.

Activity paused while awaiting CMS approval for plan submitted last quarter

For all aspects of the demonstration drawing upon Medicaid claims and encounter data, the evaluator continued running standard population indicators for 2021 and 2022 (e.g., hospitalizations) as well as exploratory work identifying relevant populations to examine demonstration hypotheses (e.g., specific service or program recipients). The evaluator began to assemble analytic datasets for summative report analyses.

Planning for evaluation of Demonstration (April 1, 2023 to June 30, 2028)

The independent evaluator had numerous internal planning meetings, exploratory meetings with potential collaborators, as well as meetings with State subject matter experts to plan the evaluation of the next demonstration (4/1/2023-6/30/2028), including:

- Received DMAHS and DDD feedback on plan for IDD-related programs for adults and got permission to submit revisions with final evaluation plans
- The evaluator prepared memos for each MCO with feedback evaluability of their CHW pilot plan and attended a meeting with DMAHS staff to discuss CHW pilot planning with MCOs, in June 2024.

The independent evaluator submitted the following revised draft evaluation plans for the 4/1/2023-6/30/2028 demonstration to DMAHS for review, after receiving comments from DMAHS and other state subject matter experts:

- Housing Supports, revised plan on 4/5/24
- Qualified Income Trusts, self attestation, and OPG attestations, revised plan on 4/11/24
- OUD/SUD, revised plan on 4/4/24
- Postpartum coverage extension, revised plans on 4/10/24 and 5/15/24
- CHW pilot, revised plan on 4/18/24
- Medically-indicated meals pilot, revised plan on 5/15/24

APPENDIX

New Jersey FamilyCare 1115 Comprehensive Demonstration Post-Award Forum Summary of Public Comments

As required by Special Terms and Condition (STC) 12.13, New Jersey held a virtual Post-Award Forum on August 29th, 2023 to afford the public with an opportunity to provide meaningful comments on the progress of the 1115 Comprehensive Demonstration (Demonstration) Renewal. To ensure widespread

stakeholder participation and encourage statewide input, the State published a detailed public notice on its website on July 25, 2023 and subsequently presented a high-level overview of the Demonstration at the Post-Award Forum. The State also established an email address specifically to accept public comments. This email address was included in all slide presentations and in the public notice that was published statewide. The Division of Medical Assistance and Health Services (DMAHS) received eight comments from a variety of stakeholders including mental health agencies, social service agencies, and parent advocates. The public's comments are summarized below.

General Comments

During the Forum and via the dedicated email inbox, comments were received on specific programs, as well as the overall implementation of the Demonstration. The majority of the respondents expressed praise and appreciation for the opportunity to provide comments and for the concepts included in the most recent renewal. Other commenters spoke to future efforts that could be undertaken and suggestions on improvements to current programs. Specifically, DMAHS was commended for ramping up its mental health service system for individuals with I/DD. Appreciation was expressed for the thoughtful and planful approach that has been taken with the integration of behavioral services into managed care and for efforts toward the implementation of interoperable electronic records. DMAHS was also applauded for the ongoing stakeholder efforts around the behavioral health integration and housing initiatives. Stakeholders were grateful for the transparency and inclusiveness they say has been demonstrated to date.

A summary of the comments received are grouped by subject area below:

Behavioral Health

Stakeholders commented on the need for more Board Certified Behavioral Analysts (BCBAs) and the diversification of service providers. In an effort to help address DHS's concern regarding the "focus on controlling and managing challenging behavior without adequate consideration of the potential for underlying mental health or medical conditions as the causes of the behavior," one stakeholder suggested utilizing various professions to expand the talent pool along with treatment modalities and care models. In addition, stakeholders would like the definition of behavioral support expanded in the demonstration language to include the development of therapeutic interventions.

Respondents commented on the Autism Adjunct Services Pilot and stated that therapies are not just for individuals under the age of 21 years. Individuals with lifelong disabilities need access as well, even more so as they mature during adulthood. Another commenter stated that when art therapy is provided, whether it is an intervention or direct service, the therapist should be a Licensed Associate Art Therapist (LAAT) or a Licensed Professional Art Therapist (LPAT). Furthermore, a commenter asked that the classification be included in the language to connect to billing and for overall congruency. Another commenter stated that there is an intersection between mental health and autism and expressed the need for more research in the area. Finally, a commenter requested that the definition of who can implement behavior plans be expanded and the age limit of 21 removed because it creates a barrier for those in need of services.

Supports Program and Community Care Program

A respondent expressed that there is a dire situation for families whose children are between the ages of 18 to 21 requiring adult DDD residential placements. Residential providers who have openings do not offer placements to youths between ages 18 and 21 unless the timing coincides with their 21st birthday. Families of members in need of Out of Home (OOH) placements are being told their children will be sent home or may be placed in institutions unless they can transition to adult DDD residential placements soon after their 21st birthday. Currently, according to the commenter,, families of youths who are aging out of DCF that are 20 years old are in limbo as neither DCF nor DDD offers OOH placements for this age and the families are forced into accepting inappropriate placements for their children. Respondent called for transparency on the status of the expansion of these services and when it will be operationalized.

Caregiver Supports Program

Stakeholders would like more transparency from the state on when this program will be operationalized. The Caregiver Support Service is designed to prevent institutionalization, therefore it is important that it is operationalized as soon as possible, as once individuals are placed in a nursing home, they are not likely to return to the community.

Self-Directed Services/Self Direction

A parent advocate expressed a need for individuals to earn a fair living wage and believes that caps on wages should be eliminated. They also stated that there needs to be additional support for Self-Directed Employees (SDEs) as they are having difficulty with self-direction due to barriers such as administrative hold ups, difficulty in providing wage increases, and no equality in pay. In addition, SDEs should be allowed to use their budget to cover rent, utilities, phone, and activities.

Another parent advocate suggested that support coordinators should assist with the single annual reapplication process and other governmental applications for services such as, rental vouchers, SNAP, and utility assistance. They also believe there is a need to streamline or eliminate cross governmental applications as it has become over burdensome and time consuming. Respondent would also like support coordinators to be paid to participate in the administrative tasks and oversight of staff.

No Wrong Door

Respondents highlighted the eligibility barrier that exists when applicants do not have appropriate trustees. They also believe that the process is too technical causing ineligibility and feels a spend down approach would be a better option. To expand access for individuals with I/DD who can benefit from these demonstration program services to live as integrated members of society, respondents suggest DMAHS should implement its QIT eligibility provision.

Nutritional Supports

A commenter encouraged the state to continue to explore other ways to fund healthy eating such as providing produce and whole foods. It was suggested Medicaid partner with meal services like Hello Fresh, Blue Apron, or Thistle to make healthy cooking easier for members.

Program Coverage and Accountability

A stakeholder raised awareness about a NJ Pediatric Health System beginning to phase out care for New Jersey children with several Medicaid managed-care plans and also called for more transparency and supervision from MCOs. Respondents questioned if the 1115 Demonstration was an avenue to provide workability coverage. Commenters also inquired when the Extension of Postpartum Coverage and continuous eligibility for Modified Adjusted Gross Income (MAGI) programs will be implemented. Respondents requested CMS inspect the conditions of the 1115 Demonstration closely and hold the State accountable for complying with Person Centered Planning (PCP) and Home and Community Based Services (HCBS) provisions.

ATTACHMENTS:

A. BUDGET NEUTRALITY WORKBOOK (SUBMITTED IN PMDA)