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Measurement, Monitoring, and Evaluation of State Demonstrations to Integrate Care for Dual Eligible Individuals

Ohio Evaluation Design Plan

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Ohio Evaluation Design Plan

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Executive Summary

The Ohio demonstration under the Financial Alignment Initiative will contract with Medicare-Medicaid Plans (hereafter referred to as Integrated Care Delivery System [ICDS] plans), to provide Medicare and Medicaid services to full-benefit Medicare-Medicaid enrollees aged 18 or older, with the following exceptions: individuals with intellectual and developmental disabilities (IDD) who are served through an IDD 1915(c) home and community-based services (HCBS) waiver or intermediate care facilities for individuals with IDD (ICF-IDD); individuals with third-party creditable health care coverage; those on a delayed Medicaid spend-down, whose Medicaid coverage is not continuous; and individuals enrolled in the Program of All-Inclusive Care for the Elderly (PACE). The ICDS plans will be responsible for delivery and management of all medical, behavioral health, and long-term services and supports (LTSS) for their enrollees. The demonstration will be offered in seven regions of three to five counties each, centered in major urban areas. Enrollees in each region will have a choice of two plans, except for one region in which three plans will be available. Plans will be paid a blended capitated rate covering all Medicare and Medicaid services under three-way contracts between ICDS plans, the State, and Centers for Medicare & Medicaid Services (CMS). The demonstration is scheduled to begin no sooner than March 1, 2014 (CMS and State of Ohio Office of Medical Assistance, 2012).

CMS contracted with RTI International to monitor the implementation of all State demonstrations under the Financial Alignment Initiative and to evaluate their impact on beneficiary experience, quality, utilization, and cost. The evaluation includes an aggregate evaluation and State-specific evaluations. This report describes the State-specific Evaluation Plan for the Ohio demonstration as of January 3, 2014. The evaluation activities may be revised if modifications are made to either the Ohio demonstration or to the activities described in the *Aggregate Evaluation Plan* (Walsh et al., 2013). Although this document will not be revised to address all changes that may occur, the annual and final evaluation reports will note areas where the evaluation as executed differs from this evaluation plan.

The goals of the evaluation are to monitor demonstration implementation, evaluate the impact of the demonstration on the beneficiary experience, monitor unintended consequences, and monitor and evaluate the demonstration's impact on a range of outcomes for the eligible population as a whole and for subpopulations (e.g., people with severe and persistent mental illness and/or substance use disorders and LTSS recipients). To achieve these goals, RTI International will collect qualitative and quantitative data from Ohio each quarter; analyze Medicare and Medicaid enrollment and claims data; conduct site visits, beneficiary focus groups, and key informant interviews; and incorporate relevant findings from any beneficiary surveys conducted by other entities. Information from monitoring and evaluation activities will be reported in a 6-month initial implementation report to CMS and the State, quarterly monitoring reports provided to CMS and the State, annual reports, and a final evaluation report. The key research questions and data sources for each are summarized in ***Table ES-1***.

The principal focus of the evaluation will be at the State level. CMS has engaged an operations support contractor to monitor fulfillment of the demonstration requirements outlined

in the Memorandum of Understanding (MOU) and three-way contracts, including ICDS-level monitoring. RTI will integrate that information into the evaluation as appropriate.

Demonstration Implementation. Evaluation of demonstration implementation will be based on case study methods and quantitative data analysis of enrollment patterns. We will monitor progress and revisions to the demonstration, and will identify transferable lessons from the Ohio demonstration through the following: document review, ongoing submissions by the State through an online State Data Reporting System (e.g., enrollment and disenrollment statistics and qualitative updates on key aspects of implementation), quarterly key informant telephone interviews, and at least two sets of site visits. We will also monitor and evaluate several demonstrating design features, including the State's progress in developing an integrated delivery system, integrated delivery system supports, care coordination/case management, benefits and services, enrollment and access to care, beneficiary engagement and protections, financing, and payment elements. ***Table 6*** in ***Section 3*** of this report provides a list of the implementation tracking elements that we will monitor for each design feature. Examples of tracking elements include State efforts to build plan and provider core competencies for serving beneficiaries with various disability types; State requirements for coordination and integration of clinical, LTSS, and behavioral health services; documentation of coordination activities between ICDS plans and community-based organizations; phase-in of new or enhanced benefits, and methods to communicate them to eligible populations; and strategies for expanding beneficiary access to demonstration benefits.

The data we gather about implementation will be used for within-State and aggregate analyses, included in a 6-month implementation report to CMS and the State, and annual reports, and will provide context for all aspects of the evaluation.

Table ES-1
Research questions and data sources

Research questions	Stakeholder interviews and site visits	Beneficiary focus groups	Claims and encounter data analysis	Demonstration statistics[1]
1) What are the primary design features of Ohio's demonstration, and how do they differ from the State's previous system?	X	X	—	X
2) To what extent did Ohio implement the demonstration as designed? What factors contributed to successful implementation? What were the barriers to implementation?	X	—	—	X
3) What impact does the Ohio demonstration have on the beneficiary experience overall and for beneficiary subgroups? Do beneficiaries perceive improvements in how they seek care, choice of care options, how care is delivered, personal health outcomes, and quality of life?	X	X	—	X
4) What impact does the Ohio demonstration have on cost and is there evidence of cost savings in the State? How long did it take to observe cost savings in the State? How were these savings achieved in the State?	—	—	X	—
5) What impact does the Ohio demonstration have on utilization patterns in acute, long-term, and behavioral health services, overall and for beneficiary subgroups?	X	X	X	X
6) What impact does the Ohio demonstration have on health care quality overall and for beneficiary subgroups?	—	—	X	X
7) Does the Ohio demonstration change access to care for medical, behavioral health, long-term services and supports (LTSS) overall and for beneficiary subgroups? If so, how?	X	X	X	X
8) What policies, procedures, or practices implemented by Ohio in its demonstration can inform adaptation or replication by other States?	X	X	—	X
9) What strategies used or challenges encountered by Ohio in its demonstration can inform adaptation or replication by other States?	X	X	—	X

— = not applicable.

[1] Demonstration statistics refer to data that the State, CMS, or other entities will provide regarding topics, including enrollments, disenrollments, grievances, appeals, and the number of Integrated Care Delivery System (ICDS) plans.

Beneficiary Experience. The impact of this demonstration on beneficiary experience is an important focus of the evaluation. Our framework for evaluating beneficiary experience is influenced by work conducted by the Center for Health Care Strategies (CHCS) on the elements of integration that directly affect beneficiary experience for Medicare-Medicaid enrollees. ***Table 8*** in ***Section 4*** of this report aligns key elements identified in the CHCS framework with the demonstration design features listed in the demonstration implementation section. The goals of these analyses are to examine the beneficiary experience and how it varies by subpopulation, and whether the demonstration has had the desired impact on beneficiary outcomes, including quality of life.

To understand beneficiary experience, we will monitor State-reported data quarterly (e.g., reports of beneficiary engagement activities), and discuss issues related to the beneficiary experience during telephone follow-up calls and site visits with the State and with stakeholders. We will also obtain data on grievances and appeals from CMS and, as available, other sources. Focus groups will include Medicare-Medicaid enrollees from a variety of subpopulations, such as people with mental health conditions, substance use disorders, LTSS needs, and multiple chronic conditions. Relevant demonstration statistics will be monitored quarterly, and quantitative and qualitative analyses of the beneficiary experience will be included in annual State-specific reports and the final evaluation report.

Analysis Overview. Quality, utilization, access to care, and cost will be monitored and evaluated using encounter, claims, and enrollment data for a 2-year predemonstration period and during the course of the demonstration. The evaluation will use an intent-to-treat (ITT) approach for the quantitative analyses, comparing the eligible population for the Ohio demonstration with a similar population that is not affected by the demonstration (i.e., a comparison group). Under the ITT framework, outcome analyses will include all beneficiaries eligible for the demonstration in the demonstration area, including those who opt out, participate but then disenroll, and those who enroll but may not seek services, and a group of similar individuals in the comparison group. This approach diminishes the potential for selection bias and highlights the effect of the demonstration on all beneficiaries in the demonstration-eligible population. RTI will compare the characteristics of those who enroll with those who are eligible but do not enroll in the care model and conduct analyses to further explore demonstration effects on demonstration enrollees, acknowledging that selection bias needs to be taken into account in interpreting the results.

Identifying the Eligible Population and Comparison Group. To identify the population eligible for the demonstration, Ohio will submit "finder files" to RTI on a quarterly basis. RTI will use this information to identify the characteristics of eligible beneficiaries for the quantitative analysis. ***Section 4.2.2.1*** of this report provides more detail on the contents of the demonstration evaluation (finder) files.

Identifying the comparison group members will entail two steps: (1) selecting the geographic area from which the comparison group will be drawn and (2) identifying the individuals who will be included in the comparison group. Because Ohio does not intend to implement its demonstration statewide, RTI will consider an in-State comparison group. We will use cluster analysis to identify potential in-State and out-of-State comparison areas that are most similar to the demonstration areas in regard to market-level variables, including costs, care

delivery arrangements, and (for out-of-State areas if needed) State policy affecting Medicare-Medicaid enrollees.

Once comparison areas are selected, all Medicare-Medicaid enrollees in those areas who meet the demonstration's eligibility criteria will be selected for comparison group membership based on the intent-to-treat study design. The comparison group will be refreshed annually to incorporate new entrants into the eligible population as new individuals become eligible for the demonstration over time. We will use propensity-score weighting to adjust for differences in individual-level characteristics between the treatment and comparison group members, using beneficiary-level data (demographics, socioeconomic, health, and disability status) and county-level data (health care market and local economic) characteristics. We will remove from the comparison group any beneficiaries with a propensity score lower than the lowest score found in the demonstration group.

The comparison areas will be determined within the first year of implementation in order to use the timeliest data available. The comparison group members will be determined retrospectively at the end of each demonstration year, allowing us to include information on individuals newly eligible or ineligible for the demonstration during that year.

Analyses. Analyses of quality, utilization, and cost in the Ohio evaluation will consist of the following:

1. A monitoring analysis to track quarterly changes in selected quality, utilization, and cost measures over the course of the Ohio demonstration.

2. A descriptive analysis of quality, utilization, and cost measures with means and comparisons for subgroups of interest, including comparison group results, for annual reports. This analysis will focus on estimates for a broad range of quality, utilization, and cost measures, as well as changes in these measures across years or subgroups of interest within each year.

3. Multivariate difference-in-differences analyses of quality, utilization, and cost measures using a comparison group.

4. A calculation of savings twice during the demonstration. RTI is developing the methodology for evaluating savings for States implementing capitated model demonstrations, which will include an analysis of spending by program (Medicaid, Medicare Parts A & B services, Medicare Part D services).

Subpopulation Analyses. It is important to understand whether the demonstration has differential effects on subpopulations as defined by disability type, or demographic or clinical characteristics, such as cognitive status, clinical complexity, and residence (community-residing or in a residential setting). RTI will identify high-priority, policy-relevant populations to analyze for Ohio to evaluate the impact of the demonstration on quality, utilization, and access to care for medical, LTSS, and behavioral health services and also to examine qualitative data gathered through interviews, focus groups, and surveys.

Descriptive analyses for annual reports will present results on selected measures stratified by subpopulations (e.g., those using and not using behavioral health services, LTSS). Multivariate analyses performed for the final evaluation will account for differential effects for subpopulations to understand whether quality, utilization, and cost are higher or lower for these groups.

Utilization and Access to Care. Medicare, Medicaid, and ICDS plan encounter data will be used to evaluate changes in the levels and types of services used, ranging along a continuum from institutional care to care provided at home (see ***Table 15*** of this report for more detail).

Quality. Across all demonstrations, RTI will evaluate a core quality measure set for monitoring and evaluation purposes that are available through claims and encounter data. RTI will obtain these data from CMS (see Table 16 of this report). We will supplement these core measures with the following:

- Additional quality measures specific to Ohio, which will be finalized within the first 6 months of implementation.
- Quality of life, satisfaction, and access to care information derived from the evaluation as discussed in ***Section 4.1*** and in ***Section 4.2.***
- HEDIS measures that ICDS plans are required to submit, as outlined in the Medicare-Medicaid Capitated Financial Alignment Model Reporting Requirements (CMS, 2013).
- Beneficiary surveys, such as HOS and CAHPS, that ICDS plans are required to report to CMS.

Cost. To determine annual total costs (overall and by payer), we will aggregate the Medicare and Medicaid per member per month (PMPM) payments paid to the ICDS plans and the costs for the eligible population that is not enrolled in the demonstration, per the intent-to-treat evaluation design. This approach will help us to detect overall cost impact and eliminate the effects of potential selection bias among beneficiaries who participate in the demonstration and those who opt out or disenroll. We will also include Part D PMPM and any PMPM reconciliation data provided by CMS in the final assessment of cost impact to ensure that all data are available. Cost savings will be calculated twice for capitated model demonstrations, using a regression-based approach. The methodology for determining cost savings for capitated model demonstrations is currently under development and will be reviewed and approved by the CMS Office of the Actuary.

Summary of Data Sources. ***Table ES-2*** displays the sources of information the RTI evaluation team will use to monitor demonstration progress and evaluate the outcomes of the Financial Alignment Demonstrations. The table provides an overview of the data that Ohio will be asked to provide and evaluation activities in which State staff will participate. As shown in this table, the evaluation team will access claims, encounter, and other administrative data from CMS. These data, and how they will be used in the evaluation, are discussed in detail in this evaluation plan and in the *Aggregate Evaluation Plan* (Walsh et al., 2013).

Table ES-2
Sources of information for the evaluation of the Financial Alignment Demonstrations

RTI will obtain data from:	Type of Data
CMS	• Encounter data (Medicare Advantage, Medicaid, and ICDS plans) • HEDIS measures • Results from HOS and CAHPS surveys • Medicare and Medicaid fee-for-service claims • Medicare Part D costs • Nursing Home data (MDS) • CMS-HCC and RXHCC risk scores • Demonstration quality measures that States are required to report to CMS (listed in MOU) • Demonstration quality measures that health plans are required to report to CMS (listed in three-way contracts or other guidance) • Other administrative data as available
State	• Detailed description of State's method for identifying eligible beneficiaries • File with monthly information identifying beneficiaries eligible for the demonstration (can be submitted monthly or quarterly)[1] • SDRS (described in detail in Section 4 of the *Aggregate Evaluation Plan*) quarterly submissions of demonstration updates, including monthly statistics on enrollments, opt-outs, and disenrollments • Participation in key informant interviews and site visits conducted by RTI team • Results from surveys, focus groups, or other evaluation activities (e.g., EQRO or Ombuds reports) conducted or contracted by the State,[2] if applicable • Other data State believes would benefit this evaluation, if applicable
Other sources	• Results of focus groups conducted by RTI subcontractor (Henne Group) • Grievances and appeals • Other sources of data, as available

CAHPS = Consumer Assessment of Healthcare Providers and Systems; EQRO = external quality review organization; HCC = hierarchical condition category; HEDIS = Healthcare Effectiveness Data and Information Set; HOS = Health Outcomes Survey; ICDS = Integrated Care Delivery System; MDS = Minimum Data Set; RXHCC = prescription drug hierarchical condition category; SDRS = State Data Reporting System.

[1] These data, which include both those enrolled and those eligible but not enrolled, will be used (in combination with other data) to identify the characteristics of the total eligible and the enrolled population. More information is provided in Section 4 of this report.

[2] States are not required to conduct or contract for surveys or focus groups for the evaluation of this demonstration. However, if the State chooses to do so, the State can provide any resulting reports from its own independent evaluation activities for incorporation into this evaluation, as appropriate.

References

Centers for Medicare & Medicaid Services (CMS): Medicare-Medicaid Capitated Financial Alignment Model Reporting Requirements. November 25, 2013. http://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/FinalCY2014CoreReportingRequirements.pdf. As obtained December 9, 2013.

Centers for Medicare & Medicaid Services and the State of Ohio Office of Medical Assistance: Memorandum of Understanding (MOU) Regarding a Federal-State Partnership to Test a Capitated Financial Alignment Model for Medicare-Medicaid Enrollees. https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/OHMOU.pdf. 2012.

Walsh, E. G., Anderson, W., Greene, A. M., et al.: Measurement, Monitoring, and Evaluation of State Demonstrations to Integrate Care for Dual Eligible Individuals: Aggregate Evaluation Plan, Contract No. HHSM500201000021i TO #3. Waltham, MA. RTI International, December 16, 2013.

1. Introduction

1.1 Purpose

The Medicare-Medicaid Coordination Office (MMCO) and Innovation Center at the Centers for Medicare & Medicaid Services (CMS) have created Financial Alignment Demonstrations for States to test integrated care models for Medicare-Medicaid enrollees. The goal of these Financial Alignment Demonstrations is to develop person-centered care delivery models integrating the full range of medical, behavioral health, and long-term services and supports (LTSS) for Medicare-Medicaid enrollees, with the expectation that integrated delivery models would address the current challenges associated with the lack of coordination of Medicare and Medicaid benefits, financing, and incentives.

CMS contracted with RTI International to monitor the implementation of the demonstrations and to evaluate their impact on quality, utilization, and cost. The evaluation includes an aggregate evaluation and State-specific evaluations.

This report describes the State-specific Evaluation Plan for the Ohio demonstration as of January 3, 2014. The evaluation activities may be revised if modifications are made to either the Ohio demonstration or to the activities described in the *Aggregate Evaluation Plan* (Walsh et al., 2013). Although this document will not be revised to address all changes that may occur, the annual and final evaluation reports will note areas where the evaluation as executed differs from this evaluation plan. This report provides an overview of the Ohio demonstration and provides detailed information on the framework for quantitative and qualitative data collection; the data sources, including data collected through RTI's State Data Reporting System (described in ***Section 3.5, Progress Indicators***, and in detail in the *Aggregate Evaluation Plan* (Walsh et al., 2013); and impact and outcome analysis (i.e., the impact on beneficiary experience and quality, utilization, access to care, and cost) that will be tailored to Ohio.

1.2 Research Questions

The major research questions of the Ohio evaluation are presented in ***Table 1*** with an identification of possible data sources. The evaluation will use multiple approaches and data sources to address these questions. These are described in more detail in ***Sections 3*** and ***4*** of this report.

Unless otherwise referenced, the summary of the Ohio demonstration is based on the Memorandum of Understanding between CMS and the State of Ohio, signed December 11, 2012 (CMS and State of Ohio Office of Medical Assistance [OMA], 2012; hereafter, MOU, 2012); the State's demonstration proposal, submitted on April 2, 2012 (State of Ohio OMA, 2012; hereafter, Ohio proposal, 2012); documents posted on the Ohio Governor's Office of Health Transformation's Integrate Medicare and Medicaid Benefits website; and discussions and e-mail communications with MMCO staff at CMS regarding the Ohio demonstration as of January 3, 2014. The evaluation design also takes into account any information we have learned through conversations with the Ohio OMA. The details of the evaluation design are covered in the three major sections that follow:

- An overview of the Ohio demonstration
- Demonstration implementation evaluation and monitoring
- Impact and outcome evaluation and monitoring.

Table 1
Research questions and data sources

Research questions	Stakeholder interviews and site visits	Beneficiary focus groups	Claims and encounter data analysis	Demonstration statistics[1]
1) What are the primary design features of Ohio's demonstration, and how do they differ from the State's previous system?	X	X	—	X
2) To what extent did Ohio implement the demonstration as designed? What factors contributed to successful implementation? What were the barriers to implementation?	X	—	—	X
3) What impact does the Ohio demonstration have on the beneficiary experience overall and for beneficiary subgroups? Do beneficiaries perceive improvements in how they seek care, choice of care options, how care is delivered, personal health outcomes, and quality of life?	X	X	—	X
4) What impact does the Ohio demonstration have on cost and is there evidence of cost savings in the State? How long did it take to observe cost savings in the State? How were these savings achieved in the State?	—	—	X	—
5) What impact does the Ohio demonstration have on utilization patterns in acute, long-term, and behavioral health services, overall and for beneficiary subgroups?	X	X	X	X
6) What impact does the Ohio demonstration have on health care quality overall and for beneficiary subgroups?	—	—	X	X
7) Does the Ohio demonstration change access to care for medical, behavioral health, long-term services and supports (LTSS) overall and for beneficiary subgroups? If so, how?	X	X	X	X
8) What policies, procedures, or practices implemented by Ohio in its demonstration can inform adaptation or replication by other States?	X	X	—	X
9) What strategies used or challenges encountered by Ohio in its demonstration can inform adaptation or replication by other States?	X	X	—	X

— = not applicable.

[1] Demonstration statistics refer to data that the State, CMS, or other entities will provide regarding topics, including enrollments, disenrollments, grievances, appeals, and the number of Integrated Care Delivery System (ICDS) plans.

2. Ohio Demonstration

2.1 Demonstration Goals

The goals of the Ohio demonstration are to improve the beneficiary experience in accessing care; increase individuals' independence and engagement; improve quality; reduce health disparities; meet both health and functional needs; improve transitions between care settings; eliminate cost-shifting between Medicare and Medicaid; and achieve cost savings for the State and Federal governments through improvements in care and coordination (MOU, 2012, p. 1).

2.2 Summary of Demonstration

Ohio will implement a capitated model that will contract with Integrated Care Delivery System (ICDS) plans to provide Medicare and Medicaid services to full-benefit Medicare-Medicaid enrollees aged 18 or older, with the exception of certain populations listed below. In order to participate in the demonstration, ICDS plans had to meet the State's requirements set forth in the Ohio Request for Applications (RFA) (RFA, 2012); CMS requirements outlined in the Medicare Advantage plan application process and in multiple sets of capitated Financial Alignment Demonstration guidance; and pass a joint CMS/State readiness review. The ICDS plans will be responsible for delivery and management of all medical, behavioral health, and long-term services and supports (LTSS) for their enrollees. The demonstration will be offered in seven regions of three to five counties each, centered in major urban areas. Enrollees in each region will have a choice of two plans, except for one region in which three plans will be available. Plans will be paid a blended capitated rate covering all Medicare and Medicaid services under three-way contracts between ICDS plans, the State, and CMS. The demonstration is scheduled to begin no sooner than March 1, 2014 (MOU, 2012).

The following groups of individuals are not eligible to enroll in the demonstration: individuals with intellectual and developmental disabilities (IDD) who are served through an IDD 1915(c) home and community-based services (HCBS) waiver or intermediate care facilities for individuals with IDD (ICF-IDD), individuals with third-party creditable health care coverage, those on a delayed Medicaid spend-down, whose Medicaid coverage is not continuous, and individuals enrolled in the Program of All-Inclusive Care for the Elderly (PACE).

Individuals enrolled in Medicare Advantage plans are eligible for the demonstration, and will be included in passive enrollment. Medicare-Medicaid enrollees who have intellectual/developmental disabilities may choose to opt into the demonstration and enroll in an ICDS plan, but would be choosing to opt out of waivers that cover habilitative services, in order to enroll in the ICDS. PACE participants are not eligible to participate in the demonstration while enrolled in a PACE plan, but may enroll in an ICDS plan if they choose to disenroll from PACE. If a demonstration enrollee elects to use hospice, he or she will remain in the ICDS plan but receive Medicare hospice and other Medicare services through Medicare Fee-for-Service, as occurs today in Medicare Advantage plans. Medicaid and Part D Medicare services would continue to be provided by the ICDS plan (MOU, 2012, p. 60).

Enrollees will retain the right to opt out of the demonstration and receive their Medicare-covered benefits through a Medicare Advantage plan or Medicare Fee-for-Service. However, Ohio will require Medicare-Medicaid enrollees to receive their Medicaid services through an ICDS plan, even if they chose to opt out of the demonstration or disenroll from an ICDS plan for Medicare services. Individuals may switch plans at any time, and beneficiaries who opt out of the demonstration may re-enroll at any time.

Medicare-Medicaid enrollees will be sent an initial information letter no less than 60 days before the passive enrollment effective date, to inform them of their opportunity to select an ICDS plan or opt out of the demonstration before the passive enrollment takes effect. Beneficiaries who fail to respond to the 60- and 30-day letters will be automatically assigned to one of the ICDS plans in their region.

After enrollment, each beneficiary will be supported by a transdisciplinary care management team, led by a care manager, which includes the enrollee, the primary care provider, the waiver service coordinator (as appropriate), and others as appropriate or as requested by the enrollee (MOU, 2012, p. 54).

ICDS plans must provide comprehensive care management services to all beneficiaries enrolled in their plans. Because individuals will have varying levels of needs, ICDS plans will assign individuals to risk levels for the purposes of resource allocation and targeting interventions based on their needs. After enrollment, each beneficiary will receive a comprehensive assessment of his or her medical, behavioral, long-term care, and social needs. Results of the comprehensive assessment will be used to determine the appropriate risk level for the individual and as the basis for developing the integrated, individualized care plan. Each individual will be supported by a care management team led by an accountable care manager and that will consist of the individual, family/caregivers, the primary care provider, specialists, and waiver service coordinator, as appropriate. Continuous monitoring of the care plan will occur and any gaps in care will be addressed in an integrated manner by the care management team including revisions to the care plan.

ICDS plans must contract with Area Agencies on Aging for waiver service coordination for enrollees aged 60 and older, and may also contract with other service coordination entities. Enrollees may choose among waiver service coordination providers. ICDS plans may provide waiver service coordination directly for enrollees under 60, or contract with another entity (MOU, 2012, p. 56).

Ohio has already implemented health homes per Section 2703 of the Affordable Care Act (Patient Protection and Affordable Care Act, 2010) on a limited basis, though health homes are not a key component of the Financial Alignment Demonstration. Ohio's health homes will serve Medicaid-eligible individuals with severe and persistent mental illness (SPMI), including Medicare-Medicaid enrollees in the Financial Alignment Demonstration. The Ohio Health Home State Plan Amendment (SPA) became effective October 1, 2012, and coverage was limited to 5 counties, including 2 ICDS demonstration counties. In these counties, ICDS plans are required to contract with health homes, and ICDS enrollees with SPMI may choose to have their care management services provided by a health home or an ICDS plan. Health homes will be Community Behavioral Health Centers that are certified by the Ohio Department of Mental

Health and Addiction Services (Ohio Health Home SPA, 2012). The State intended to expand the SPMI health homes option to the remaining 83 counties during 2013 (State of Ohio OMA, n.d.).

Table 2 provides a summary of the key characteristics of the Ohio demonstration compared with the system that currently exists for demonstration-eligible beneficiaries.

Table 2
Key features of Ohio's model predemonstration and during the demonstration

Key features	Predemonstration	Demonstration[1]
Summary of covered benefits		
Medicare	Medicare Parts, A, B, and D	Medicare Parts A, B, and D
Medicaid	Medicaid State Plan services and HCBS waivers	Medicaid State Plan services and HCBS waivers
Payment method (capitated/ FFS/MFFS)		
Medicare	FFS or capitated	Capitated
Medicaid (capitated managed care or FFS)		
Primary/medical	FFS	Capitated
Behavioral health	FFS	Capitated
LTSS (excluding HCBS waiver services)	FFS	Capitated
HCBS waiver services	FFS	Capitated
Care coordination/case management		
Care coordination for medical, behavioral health, LTSS and social needs, and by whom	N/A for medical. In 5 counties care coordination for all services is provided by community behavioral health centers designated as health homes for persons with SPMI.	ICDS plans. Individuals with SPMI who are eligible for health home services can choose to have care coordination of all services provided by either the plan or a health home, if available in their area. Plans must contract with health homes in their service areas.
Care coordination/case management for HCBS waivers and by whom	Case management for the 5 HCBS waivers used by the demonstration eligible population is provided by AAAs or other State-contracted case management agencies.	ICDS plans must contract with AAAs for waiver service coordination for enrollees 60 and older, and may also contract with other entities. Enrollees 60 and older may choose among waiver service coordination providers. ICDS plans may also provide waiver service coordination directly for enrollees under 60, or contract with another entity for this service.
Clinical, integrated, or intensive care management	N/A	Single care manager for enrollee through the ICDS plan, or through health homes for people with SPMI (in counties with health homes).

(continued)

Table 2 (continued)
Key features of Ohio model predemonstration and during the demonstration

Key features	Predemonstration	Demonstration[1]
Enrollment/assignment		
Enrollment method	N/A. FFS. Medicare-Medicaid enrollees are not eligible to enroll in Medicaid managed care.	Enrollment in an ICDS plan is mandatory for Medicaid services, but beneficiaries may opt out of the demonstration (i.e., opt out of receiving Medicare services from an ICDS plan). Beneficiaries who do not select a plan or opt out of the demonstration, including individuals in Medicare Advantage plans, will be passively enrolled in the demonstration and assigned to an ICDS plan.
Attribution/assignment method	N/A	N/A
Implementation		
Geographic area	N/A	Regional—7 regions of 3 to 5 counties each, including major urban centers (Akron, Canton, Cincinnati, Cleveland, Columbus, Dayton, Toledo, and Youngstown).
Phase-in plan	N/A	The first effective date for opt-in enrollments in all regions is no sooner than March 1, 2014. Passive enrollments are scheduled to be effective no sooner than April 1, and will be rolled out by region.
Implementation date	N/A	ICDS plans will begin providing coverage for enrollees no sooner than March 1, 2014, starting with opt-in enrollees.

AAA = Area Agency on Aging; FFS = fee-for-service; HCBS = home and community-based services; ICDS = Integrated Care Delivery System; LTSS = long-term services and supports; N/A = not applicable; SPMI = severe and persistent mental illness.

[1] Information related to the demonstration in this table is from the Memorandum of Understanding (MOU, 2012) and Ohio's Health Home State Plan Amendment (Ohio Health Home SPA, 2012).

In 2011, approximately 182,000 individuals in Ohio were fully eligible for both Medicare and Medicaid. Nearly two-thirds (63 percent) will be eligible for the demonstration: about 115,000 individuals who live in the seven target regions and meet the demonstration eligibility criteria.

Ohio will include individuals with SPMI in the demonstration. Individuals with intellectual and developmental disabilities who are not enrolled in an HCBS waiver or living in an ICF-IDD will also be eligible for the demonstration.

The characteristics of the population eligible to participate in the demonstration by care setting and HCBS waiver status are presented in ***Table 3***.

Table 3
Characteristics of eligible population residing in demonstration areas for CY 2010

Condition	No. of beneficiaries	Percentage of eligible population
Severe and persistent mental illness (included in other groups)	12,326 [1]	11%
Subpopulations (residing in facilities)[2]		
Beneficiaries age 18–64	4,204 [1]	4%
Beneficiaries age 65+	28,743 [1]	25%
Subpopulations (residing in the community)[3]		
Beneficiaries age 18–64 in the community—waiver	4,994 [1]	4%
Beneficiaries age 65+ in the community—waiver	19,545 [1]	17%
Beneficiaries age 18–64 in the community—nonwaiver	36,791 [1]	32%
Beneficiaries age 65+ in the community—nonwaiver	20,695 [1]	18%
Total individuals potentially eligible for demonstration	114,972 [4]	100%

[1] Estimated populations extrapolated from "ICDS Eligible Population—Member Months," ICDS Data Book, http://jfs.test.ohio.gov/OHP/bmhc/ICDSRFALibrary.stm. As obtained on February 12, 2013.

[2] Nursing facilities. Residents of intermediate care facilities for individuals with intellectual and developmental disabilities (ICF-IDDs) are not eligible to enroll in the demonstration.

[3] Community Waiver: Individuals who were enrolled in an HCBS waiver during the month and did not meet the criteria for the "institutionalized" definition. Community Non-waiver: All Integrated Care Delivery System (ICDS)–eligible individuals who did not meet "institutionalized" or "community waiver" criteria for the month.

[4] Ohio Department of Job and Family Services Office of Health Plans: State Demonstration to Integrate Care for Medicare-Medicaid Enrollees: Proposal to the Center for Medicare and Medicaid Innovation. Columbus, OH. Department of Job and Family Services, Office of Health Plans, April 2, 2012. Appendix C—Proposed ICDS Target Populations by Region.

As shown in ***Table 4***, the total Medicaid spending on Medicare-Medicaid enrollees making up the demonstration's eligible population (those eligible to participate in the demonstration had it been operational) was $2.5 billion in FY 2011. The vast majority (88 percent) of Medicaid services spending on the eligible population was for institutional services (65 percent) or community-based LTSS (23 percent). Information on total Medicare expenditures for the eligible population was not available in the State's proposal.

Table 4
Total expenditures for Medicare-Medicaid enrollees aged 18+, residing in demonstration area, FY 2011

Population	Medicaid expenditures	Medicare expenditures	Total expenditures
Eligible population	$2.5 billion	Not available	Not available

SOURCE: Ohio Department of Job and Family Services Office of Health Plans: State Demonstration to Integrate Care for Medicare-Medicaid Enrollees: Proposal to the Center for Medicare and Medicaid Innovation. Columbus, OH. Department of Job and Family Services, Office of Health Plans, April 2, 2012; p. 6.

2.3 Relevant Historical and Current Context

History/Experience with Managed Care. Medicaid managed care has a long history in Ohio. The State first offered managed care as an optional program for children and parents in 1978, originally in a limited number of counties. In 2006, it was made mandatory statewide for children and parents, and also for physical health services for Medicaid-only individuals in the aged, blind, and disability (ABD) population. However, individuals living in institutions or using HCBS waivers were not eligible to enroll, nor were Medicare-Medicaid enrollees. Ohio's Medicare Advantage penetration rate was 36 percent in 2012, tied for sixth highest among all States (Kaiser, 2012, p. 5).

Other Initiatives. The State reports considerable progress toward rebalancing its long-term services and supports system. The Preadmissions Screening System Providing Options and Resources Today (PASSPORT) waiver provides services to more than 32,000 individuals daily (Ohio Governor's Office of Health Transformation, 2012). However, the State still ranks in the top quintile for per capita Medicaid spending on nursing facilities, and the ratio of spending on institutions versus HCBS exceeds the national average (Ohio proposal, 2012, p. 5). CMS has approved the State's request for a new, consolidated waiver that will provide HCBS to all individuals aged 18 to 64 with physical disabilities, and those 65 and older, who qualify for waiver services under the demonstration. The waiver will combine the services currently offered in five different HCBS waivers to provide individuals with more choice of services. Children under 18 and individuals served by IDD waivers will not be covered by the consolidated waiver (Ohio proposal, 2012, p. 31).

The State will require ICDS plans to participate in efforts to advance the priorities and goals of Ohio Medicaid's Quality Strategy, including the following Health and Human Services (HHS)/CMS initiatives: Partnership for Patients; Million Hearts Campaign; HHS Action Plan to Reduce Racial and Ethnic Health Disparities; and the Community Based Care Transition Program. The State's own initiatives relevant to the demonstration include a quality improvement effort to reduce emergency department visits called IMPROVE (Implement Medicaid Programs for the Reduction of Avoidable Visits to the Emergency Department) and a State-funded initiative to promote the all-payer Patient-Centered Medical Home model through workforce training in pilot practices (Ohio proposal, 2012, p. 30). The Cincinnati-Dayton region is also participating in the CMS-sponsored Comprehensive Primary Care Initiative. Medicare is collaborating with public and private insurers to strengthen primary care in this multi-payer initiative, which will involve 75 primary care practices in a region that includes Southwest Ohio and Northern Kentucky (NASHP, 2013).

3. Demonstration Implementation Evaluation

3.1 Purpose

The evaluation of the implementation process is designed to answer the following overarching questions about Ohio's demonstration:

- What are the primary design features of the Ohio demonstration, and how do they differ from the State's previous system available to the demonstration eligible population?
- To what extent did Ohio implement the demonstration as designed? What factors contributed to successful implementation? What were the barriers to implementation?
- What State policies, procedures, or practices implemented by Ohio can inform adaptation or replication by other States?
- Was the demonstration more easily implemented for certain subgroups?
- How have beneficiaries participated in the ongoing implementation and monitoring of the demonstration?
- What strategies used or challenges encountered by Ohio can inform adaptation or replication by other States?

3.2 Approach

The evaluation team will examine whether the demonstration was implemented as designed and will look at modifications to the design features that were made during implementation; any changes in the time frame or phase-in of the demonstration; and other factors that facilitated or impeded implementation. This section will discuss the following:

- Monitoring implementation of the demonstration by key demonstration design features
- Implementation tracking elements
- Progress indicators
- Data sources
- Interview questions and implementation reports

3.3 Monitoring Implementation of the Demonstration by Key Demonstration Design Features

The major design features of the Ohio demonstration are described using a common framework that RTI will apply to all of the Financial Alignment Demonstrations as follows:

- Integrated delivery system
- Integrated delivery systems supports
- Care coordination/case management
- Benefits and services
- Enrollment and access to care
- Beneficiary engagement and protections
- Financing and payment
- Payment elements

Our analysis of the implementation of the Ohio demonstration will be organized by these key demonstration design features. This framework will be used to define our areas of inquiry, structure the demonstration variables we track, organize information from our data collection sources, and outline our annual report. ***Table 5*** illustrates the key components of each design feature that we will monitor as part of the implementation evaluation. Our goal is to frame analysis at the level of policy or practice with examples of how the intended design features and their key components translate at the point of service delivery.

Table 5
Demonstration design features and key components

Design feature	Key components
Core components of integrated delivery systems (how the delivery system is organized/integrated; interrelationships among the core delivery system components)	• ICDS plans • Primary care • LTSS • Behavioral health services • Integration functions that bridge delivery systems and roles of community-based organizations
Integrated delivery systems supports	• Care team composition • Health IT applied throughout the demonstration (at State level, by ICDS plans, at provider level or other) • Data (Medicare claims or encounter data) and other feedback to ICDS plans, medical/health homes, other providers (by the State or other entities)
Care coordination/case management (by subpopulation and/or for special services) • Medical/primary • LTSS • Behavioral health services • Integration of care coordination	• Assessment process • Service planning process • Care management targeting process • Support of care transitions across settings • Communication and hand-offs between care coordinators/case managers and providers

(continued)

Table 5 (continued)
Demonstration design features and key components

Design feature	Key components
Benefits and services	• Scope of services/benefits • New or enhanced services • Excluded services • Service authorization process
Enrollment and access to care	• Integrated enrollment and access to care • Provider accessibility standards • Marketing/education protocols • Enrollment brokers • Beneficiary information and options counseling • Opt-out, disenrollment, and auto-assignment policy • Assignment/referrals to providers, health homes, medical homes • Phased enrollment of eligible populations • Workforce development for worker supply and new functions
Beneficiary engagement and protections	• State policies to integrate Medicare and Medicaid grievances and appeals • Quality management systems • Ongoing methods for engaging beneficiary organizations in policy decisions and implementation • Approaches to capture beneficiary experience, such as surveys and focus groups
Demonstration financing model and methods of payment to plans and providers	• Financing model—capitation • Entities to which the State is directly making payments • Innovative payment methods to ICDS plans and/or to providers
Elements of payments to ICDS plans and providers	• Incentives • Risk adjustment

ICDS = Integrated Care Delivery System; IT = information technology; LTSS = long-term services and supports.

3.4 Implementation Tracking Elements

Through document review and interviews with State agency staff, we will identify and describe the delivery system for Medicare-Medicaid enrollees in the eligible population. This will enable us to identify key elements that Ohio intends to modify through the demonstration and measure the effects of those changes. Using a combination of case study methods, including document review, and telephone interviews, we will conduct a descriptive analysis of Ohio's key demonstration features.

The evaluation will analyze how Ohio is carrying out its implementation plan and track any changes it makes to its initial design as implementation proceeds. We will identify both planned changes that are part of the demonstration design (e.g., phasing in new populations) and operational and policy modifications Ohio makes based on changing circumstances. Finally, we anticipate that, in some instances, changes in the policy environment in the State will trigger alterations to the original demonstration design.

During site visit interviews and our ongoing communication with the State, we will collect detailed information on how Ohio has structured care coordination for beneficiaries enrolled in the demonstration. The evaluation will analyze the scope of care coordination responsibilities assigned to ICDS plans, the extent to which they conduct these functions directly or through contract, and internal structures established to promote service integration. We will also identify ways that the scope of care coordination activities conducted under the demonstration by ICDS plans compares to the State's approach in their capitated model programs serving other populations.

We will also collect data from the State to track implementation through the State Data Reporting System (SDRS). The State will submit quarterly demonstration statistics and qualitative updates through the SDRS (described in ***Section 3.5, Progress Indicators***, and in detail in the *Aggregate Evaluation Plan* [Walsh et al., 2013]). RTI will generate reports based on these data and conduct telephone calls with the State demonstration director as needed to understand Ohio's entries. We will make additional calls to State agency staff and key informants as needed to keep abreast of demonstration developments. We will use site visit interviews to learn more about what factors are facilitating or impeding progress or leading to revisions in the Ohio demonstration implementation.

Table 6 shows the types of demonstration implementation elements we will track using State submissions to the SDRS, quarterly calls with State demonstration staff, other interviews, and site visits.

Table 6
Implementation tracking elements by demonstration design feature

Design feature	Tracking elements
Integrated delivery system	• Three-way contracts with ICDS plans • Documentation of coordination activities between ICDS plans and community-based organizations • New waiver authorities submitted for the demonstration and approved • Emergence of new health homes • Strategies for integrating primary care, behavioral health, and LTSS (as documented in State policies, contracts, or guidelines) • Recognition and payment for care/services by nontraditional workers • Innovative care delivery approaches adopted by the demonstration
Integrated delivery system supports	• Support providers with dissemination and implementation of evidence-based practice guidelines • Decision-support tools provided or supported by State (e.g., practice-level reporting on QIs) • State efforts to build ICDS plans and provider core competencies for serving beneficiaries with various types of disabilities • Provision of regular feedback to ICDS plans and providers on the results of their performance measures
Care management	• Adoption of person-centered care coordination practices • State systems for collecting data on care coordination use • As available, care coordination activities directed to individual enrollees • State requirements for assessment and care planning • State requirements for coordination and integration of clinical, LTSS, and behavioral health services • State approaches to stratify care coordination intensity based on individual needs • State requirements for care transition support, medication reconciliation, notification of hospitalizations • State actions to facilitate adoption of EMR and EHR • Use of informatics to identify high-risk beneficiaries
Benefits and services	• Phase-in of new or enhanced benefits, and methods to communicate them to enrollees and potential enrollees • Adoption of evidence-based practices and services (e.g., use of chronic disease self-management programs by practices, fall prevention programs, other)

(continued)

Table 6 (continued)
Tracking elements by demonstration design feature

Design feature	Tracking elements
Enrollment and access to care	• State efforts to provide integrated consumer information on enrollment, benefits, and choice of ICDS plans/providers • Options counseling and information provided by Aging and Disability Resource Centers and State Health Insurance Assistance Programs • Initiatives to increase enrollment in the demonstration • Strategies for expanding beneficiary access to demonstration benefits • Emergence of new worker categories/functions (e.g., health coaches, community care workers)
Beneficiary engagement and protections	• Strategies implemented to engage beneficiaries in oversight of the demonstration • Quality management strategy, roles, and responsibilities • Implementation of quality metrics • Adoption of new State policies for beneficiary grievances and appeals based on demonstration experience
Financing and payment	• Revisions to the demonstration's initial payment methodology, including risk-adjustment methodology • Risk-mitigation strategies • Performance incentive approaches • Value-based purchasing strategies

EHR = electronic health records; EMR = electronic medical records; ICDS=Integrated Care Delivery System; LTSS-long-term services and supports; QIs = quality improvement initiatives.

3.5 Progress Indicators

In addition to tracking implementation of demonstration design features, we will also track progress indicators, including growth in enrollment and disenrollment patterns, based on Ohio's demonstration data. These progress indicators will be reported quarterly by Ohio through the SDRS, which will be the evaluation team's tool for collecting and storing information and for generating standardized tables and graphs for quarterly monitoring reports for CMS and the State. The primary goals of the system are to serve as a repository for up-to-date information about the Ohio demonstration design and progress, to capture data elements on a quarterly basis, and to monitor and report on demonstration progress by individual States and the demonstration as a whole. More detail on the SDRS can be found in the *Aggregate Evaluation Plan* (Walsh et al., 2013).

Table 7 presents a summary of progress indicators developed to date. The list of progress indicators may be refined in consultation with CMS as needed. RTI will provide trainings and an instruction manual to assist States in using the SDRS.

Table 7
Examples of progress indicators

Indicator
Eligibility
No. of beneficiaries eligible to participate in the demonstration
Enrollment
Total no. of beneficiaries enrolled in the demonstration
No. of beneficiaries newly enrolled in the demonstration as of the end of the given month
No. of beneficiaries automatically (passively) enrolled in the demonstration
Disenrollment
No. of beneficiaries who opted out of the demonstration prior to enrollment
No. of beneficiaries who voluntarily disenrolled from the demonstration
No. of beneficiaries whose enrollment in the demonstration ended involuntarily (e.g., died, moved out of area, lost Medicaid eligibility, were incarcerated)
Demonstration service area
Whether demonstration is currently statewide vs. in specific counties or geographic areas (and provide list if in specific geographic areas)
Specific to capitated model demonstrations
No. of three-way contracts with ICDS plans
Specific to demonstrations that use health homes
No. of Section 2703–designated health homes participating in the demonstration
No. of participating enrollees served by 2703 health homes

2703 health homes = as defined by Section 2703 of the Affordable Care Act; ICDS=Integrated Care Delivery System.

3.6 Data Sources

The evaluation team will use a variety of data sources to assess whether the Ohio demonstration was implemented as planned; identify modifications made to the design features during implementation; document changes in the time frame or phase-in of key elements; and determine factors that facilitated implementation or presented challenges. These data sources include the following:

- **State policies and State requirements for provider and plan agreements:** The evaluation team will review a wide range of State-developed documents that specify Ohio's approach to implementing its demonstration in order to develop a baseline profile of its current delivery system. Review of Ohio's agreements with CMS articulated through the demonstration Memorandum of Understanding (MOU), waivers, contracts, and State Plan Amendments will further enhance our understanding of Ohio's approach.

- **Demonstration data (collected via the State Data Reporting System):** On a quarterly basis, we will collect data from Ohio to inform ongoing analysis and feedback to the State and CMS throughout the demonstration. Specifically, we will

collect data to track policy and operational changes and progress indicators that are mostly numeric counts of key demonstration elements presented in ***Table 7***. These demonstration data also may include specific information provided by CMS or other entities engaged in this demonstration and incorporated into the State Data Reporting System.

- **State agency staff, stakeholders, selected care coordination organizations, and ICDS plans:** There will be at least two sets of site visits; the first one will occur within 6 months of demonstration implementation. Using two-person teams, supplemented with telephone interviews, we will obtain perspectives from key informants on progress to date, internal and external environmental changes, reasons Ohio took a particular course, and current successes and challenges. In addition to the site visits, and interim calls for clarification about State data submitted to the reporting system, in consultation with CMS we will develop a schedule of quarterly telephone interviews with various individuals involved in the demonstration.

  In addition to consumer advocates, as discussed in ***Section 4.1, Beneficiary Experience***, candidates for key informant interviews on demonstration implementation include the following:

  – Representatives from demonstration advisory council
  – Representatives from CMS–State Contract Management Team
  – State officials, such as:
    - Director of the Office of Medical Assistance
    - Director of Governor's Office of Health Transformation
    - Deputy Medicaid director for policy and programs
    - ICDS program coordinator
    - Contract managers from the Contracted Customer Service and Integrated Contracting Unit
    - Ohio Medicaid finance managers
    - Representatives from the State agencies administering programs that serve Medicare-Medicaid enrollees aged 18 or older, including the Department of Aging, the Department of Health, the Department of Mental Health, and the Department of Alcohol and Drug Addiction Services
  – Representatives from selected ICDS plans
  – Representatives from health home providers
  – Representatives from other providers and provider associations
  – Area Agency on Aging
  – Representatives from entities providing options counseling for the demonstration
  – Representatives from the demonstration Ombuds program

The site visit interview protocols used in the evaluation will contain a core set of questions that allow us to conduct an aggregate evaluation, questions specific to the financial alignment model (capitated), as well as a few questions that are specific to the Ohio demonstration. Questions tailored to the key informants in Ohio will be developed once the demonstration is implemented, and will be provided to the State in advance of the site visit. The site visit interview protocols with core questions are provided in the *Aggregate Evaluation Plan* (Walsh et al., 2013), and will also be tailored for Ohio after the demonstration begins. In advance of the site visits, the RTI team will contact the State to determine the appropriate individuals to interview. We will work with the State to schedule the site visit and the on-site interviews. We will develop an interview schedule that best suits the needs of State and key informants we plan to interview.

3.7 Analytic Methods

Evaluation of the Ohio demonstration implementation will be presented in an initial report to CMS and the State covering the first 6 months of implementation, in annual State-specific evaluation reports, and integrated into annual aggregate report comparing implementation issues and progress across similar demonstrations and across all demonstrations, as appropriate. We will collect and report quantitative data quarterly as noted in ***Table 7***, Examples of Progress Indicators, through the State Data Reporting System. We will integrate these quantitative data with qualitative data we will collect through site visits and telephone interviews with State agency staff and other key informants and include these data in the annual reports and the final evaluation report. These data will provide context for interpreting the impact and outcomes related to beneficiary experience, quality, utilization, and costs, and enable us to analyze (1) the changes Ohio has made to the preexisting delivery systems serving Medicare-Medicaid enrollees, (2) challenges Ohio has met, and (3) approaches that can inform adaptation or replication by other States.

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4. Impact and Outcomes

4.1 Beneficiary Experience

4.1.1 Overview and Purpose

The evaluation will assess the impact of the Ohio demonstration on beneficiary experience. Using mixed methods (i.e., qualitative and quantitative approaches), we will monitor and evaluate the experience of beneficiaries, their families, and caregivers. Our methods will include the following:

- the beneficiary voice through focus groups and stakeholder interviews conducted by RTI, and results of surveys that may be conducted by Ohio, CMS, or other entities (e.g., Consumer Assessment of Healthcare Providers and Systems [CAHPS]);
- Ohio demonstration data and data from other sources submitted via the State Data Reporting System (SDRS; e.g., data on enrollments, disenrollments, appeals, grievances, stakeholder engagement activities);
- claims and encounter data obtained from CMS to analyze utilization as well as access to services and outcomes for key quality measures; and
- interviews with Ohio demonstration staff during site visits or telephone interviews with RTI.

Table 8 (described in more detail below) shows the range of topics and data sources we will use to monitor and evaluate beneficiary experience. We are interested in the perspective of the beneficiaries themselves, determining specifically the impact of the demonstration on their access to needed services, the integration and coordination of services across settings and delivery systems, provider choice, enrollee rights and protections, and the provision of person-centered care. In the process, we will identify what has changed for beneficiaries since their enrollment in the demonstration and its perceived impact on their health and well-being.

This section of the evaluation plan focuses specifically on the methods we will use to monitor and evaluate beneficiary experience such as focus groups with beneficiaries and interviews with consumer and advocacy groups. We also discuss information about data we will obtain from Ohio through interviews and the SDRS, and results of beneficiary surveys that may be administered and analyzed independent of this evaluation by the State, CMS, or other entities.

Through beneficiary focus groups and key stakeholder interviews (i.e., consumer and advocacy group members), we also will explore whether we can identify specific demonstration features in Ohio that may influence replication in other States. We will also collect information from State demonstration staff and CMS or other entities that reflects the beneficiaries' experiences (e.g., grievances and appeals, disenrollment patterns) using RTI's State Data Reporting System. ***Section 3, Demonstration Implementation Evaluation***, describes topics we will monitor and document through interviews with Ohio demonstration staff and document reviews, including consumer protections and other demonstration design features intended to enhance the beneficiary experience. Refer to ***Section 4.2*** for a discussion of the use of claims and

encounter data to establish baseline information about the beneficiaries eligible for the demonstration, and how we will use these data to inform our understanding of the impact of the State's demonstration on its access to care and health outcomes.

Specifically, we will address the following research questions in this section:

- What impact does the Ohio demonstration have on the beneficiary experience overall and for beneficiary subgroups?
- What factors influence the beneficiary enrollment decision?
- Do beneficiaries perceive improvements in their ability to find needed health services?
- Do beneficiaries perceive improvements in their choice of care options, including self-direction?
- Do beneficiaries perceive improvements in how care is delivered?
- Do beneficiaries perceive improvements in their personal health outcomes?
- Do beneficiaries perceive improvements in their quality of life?

4.1.2 Approach

This mixed-methods evaluation will combine qualitative information from focus groups and key stakeholder interviews with quantitative data related to beneficiary experience derived from the RTI State Data Reporting System and findings from surveys that may be conducted independently by Ohio, CMS, or other entities (e.g., CAHPS). Qualitative data will be obtained directly from a beneficiary or beneficiary representative through focus groups, and interviews. To avoid potential bias or conflict of interest, we will apply a narrow definition of "representative" to include only family members, advocates, or members of organizations or committees whose purpose is to represent the interest of beneficiaries and who are not service providers or do not serve in an oversight capacity for the initiative. Although no baseline qualitative data are available, beneficiaries will be asked about their experience before the demonstration and how it may have changed during the course of the demonstration.

Our framework for evaluating beneficiary experience is influenced by work conducted by the Center for Health Care Strategies (CHCS), which identified the essential elements of integration affecting beneficiary experience, including the care process and quality of life (Lind and Gore, 2010). Its work is intended to guide the design of integrated care systems for Medicare-Medicaid enrollees and to do so in ways that strengthen the beneficiary experience in the areas defined in ***Table 8***.

Table 8 aligns key elements identified in the CHCS framework with the demonstration design features described in ***Section 3, Demonstration Implementation Evaluation***. We modified some elements of the CHCS framework to reflect that not all Medicare-Medicaid enrollees require intensive services as suggested by the original CHCS language used when describing comprehensive assessments and multidisciplinary care teams. For each key element, we identify the impact on beneficiary experience and detail the data sources that RTI will use to obtain the information.

Table 8
Methods for assessing beneficiary experience by beneficiary impact

Direct measure	Key stakeholder interviews	Beneficiary focus groups	Recommended survey question[1]	Ohio demonstration data[2]	Interviews with Ohio agency staff on demonstration implementation
Integrated delivery system					
Choice					
Beneficiaries have choice of medical, behavioral, and LTSS *services*.	X	X	X	X	X
Beneficiaries have choice of medical, behavioral, and LTSS *providers* within the network.	X	X	X	X	X
Beneficiaries have choice to self-direct their care.	X	X	—	X	X
Beneficiaries are empowered and supported to make informed decisions.	X	X	—	—	—
Provider network					
Beneficiaries report that providers are available to meet routine and specialized needs.	X	X	X	X	—
Beneficiaries report that LTSS and behavioral health are integrated into primary and specialty care delivery.	X	X	—	X	—
Beneficiary engagement					
Beneficiaries consistently and meaningfully have the option to participate in decisions relevant to their care.	X	X	X	X	—
There are ongoing opportunities for beneficiaries to be engaged in decisions about the design and implementation of the demonstration.	X	X	—	—	X

(continued)

Table 8 (continued)
Methods for assessing beneficiary experience by beneficiary impact

Direct measure	Key stakeholder interviews	Beneficiary focus groups	Recommended survey question[1]	Ohio demonstration data[2]	Interviews with Ohio agency staff on demonstration implementation
Streamlined processes					
Beneficiaries can easily navigate the delivery system.	X	X	—	X	—
Reduced duplication of services					
Beneficiary burden is reduced through elimination of duplicative tests and procedures.	—	—	—	X	—
Enrollment and access to care					
Enrollment					
Beneficiaries have choices and assistance in understanding their enrollment options.	X	X	—	X	X
Beneficiaries report ease of disenrollment.	X	X	—	X	—
Rate of beneficiaries who opt out of enrolling into demonstration.	—	—	—	X	—
Rate of disenrollment from the demonstration by reason.	—	—	—	X	—
Access to care					
Beneficiaries can access the full range of scheduled and urgent medical care, behavioral health services, and LTSS.	X	X	—	X	—
Beneficiaries report improved quality of life due to access to the full range of services.	X	X	X	—	—
Beneficiaries report that waiting times for routine and urgent primary and specialty care are reasonable.	X	X	—	X	—

(continued)

Table 8 (continued)
Methods for assessing beneficiary experience by beneficiary impact

Direct measure	Key stakeholder interviews	Beneficiary focus groups	Recommended survey question[1]	Ohio demonstration data[2]	Interviews with Ohio agency staff on demonstration implementation
Health Outcomes					
Beneficiary health rating.	—	—	X	—	—
Quality of Life					
Days free from pain.	—	—	X	—	—
Beneficiaries get the social and emotional supports they need.	—	X	X	—	—
Beneficiaries report that they are satisfied with their life.	—	X	X	—	—
Cultural appropriateness					
Beneficiaries have access to multilingual and culturally sensitive providers.	X	X	—	X	X
Beneficiaries report that written and oral communications are easy to understand.	X	X	—	X	—
Delivery systems supports					
Data sharing and communication					
Information is available and used by beneficiaries to inform decisions.	X	X	—	—	X
Beneficiaries report that providers are knowledgeable about them and their care history.	X	X	—	X	—
Beneficiaries have adequate discharge and referral instructions.	X	X	—	X	X
Beneficiaries report that providers follow up after visits or discharge.	X	X	—	X	—
Beneficiaries understand their options to specify that personal health data not be shared.	X	X	—	X	—

(continued)

Table 8 (continued)
Methods for assessing beneficiary experience by beneficiary impact

Direct measure	Key stakeholder interviews	Beneficiary focus groups	Recommended survey question[1]	Ohio demonstration data[2]	Interviews with Ohio agency staff on demonstration implementation
Care management					
Assessment of need					
Assessment process integrates/addresses health, behavioral health, and LTSS.	X	X	—	X	X
Medical providers actively participate in individual care planning.	—	X	X	—	—
Beneficiaries report active participation in the assessment process.	X	X	—	X	—
Person-centered care					
Care is planned and delivered in a manner reflecting a beneficiary's unique strengths, challenges, goals, and preferences.	X	X	—	X	—
Beneficiaries report that care managers have the skills and qualifications to meet their needs.	—	X	X	—	—
Beneficiaries report that providers listen attentively and are responsive to their concerns.	X	X	X	X	—
Coordination of care					
The system facilitates timely and appropriate referrals and transitions within and across services and settings.	X	X	X	X	—
Beneficiaries have supports and resources to assist them in accessing care and self-management.	X	X	—	X	—
Beneficiaries report ease of transitions across providers and settings.	X	X	X	X	—

(continued)

Table 8 (continued)
Methods for assessing beneficiary experience by beneficiary impact

Direct measure	Key stakeholder interviews	Beneficiary focus groups	Recommended survey question[1]	Ohio demonstration data[2]	Interviews with Ohio agency staff on demonstration implementation
Family and caregiver involvement					
Beneficiaries have the option to include family and/or caregivers in care planning.	X	X	—	X	—
The family or caregiver's skills, abilities, and comfort with involvement are taken into account in care planning and delivery.	X	X	—	X	—
Benefits and services					
Awareness of covered benefits					
Beneficiaries are aware of covered benefits.	X	X	—	X	—
Availability of enhanced benefits					
The demonstration covers important services to improve care outcomes that are not otherwise available through Medicaid or Medicare program.	—	—	—	X	X
Flexible benefits are available to meet the needs of beneficiaries.	—	—	—	X	X
Awareness of enhanced benefits					
Beneficiaries are aware of enhanced benefits and use them.	X	X	—	X	—
Beneficiary safeguards					
Beneficiary protections					
Beneficiaries understand their rights.	X	X	—	X	—
Beneficiaries are treated fairly, are informed of their choices, and have a strong and respected voice in decisions about their care and support services.	X	X	—	X	—

(continued)

Table 8 (continued)
Methods for assessing beneficiary experience by beneficiary impact

Direct measure	Key stakeholder interviews	Beneficiary focus groups	Recommended survey question[1]	Ohio demonstration data[2]	Interviews with Ohio agency staff on demonstration implementation
Complaints, grievances, and appeals					
Beneficiaries have easy access to fair, timely, and responsive processes when problems occur.	X	X	—	X	—
Number and type of beneficiary complaints, grievance, and appeals.	—	—	—	X	—
Advocacy/member services					
Beneficiaries get needed assistance in exercising their rights and protections.	X	X	—	X	—
Finance and payment					
Provider incentives					
Beneficiary experience is taken into account when awarding provider and plan incentives.	—	—	—	—	X
Rate of auto-assignment (if available).	—	—	—	X	—
Rate of change of PCP requests, if available	—	—	—	X	—

— = No data for cell; HCBS = home and community-based services; LTSS = long-term services and supports; PCP = primary care provider.

[1] The evaluation team will recommend questions to add to surveys conducted by Ohio or CMS.

[2] Drawn from State Data Reporting System, RTI analysis of administrative data, Consumer Assessment of Healthcare Providers and Systems (CAHPS) or Health Outcomes Survey (HOS) results, or from other beneficiary surveys that may be conducted by the State or other entities.

As shown in ***Table 8***, we will solicit direct feedback from beneficiaries served through the demonstration to determine how closely their experience compares to the desired outcomes (improvements in personal health outcomes, quality of life, how beneficiaries seek care, choice of care options, and how care is delivered). We will include topics specific to the demonstration and supplement our understanding of direct beneficiary experience with key stakeholder interviews (e.g., consumer and advocacy groups), a review of enrollment and disenrollment, grievances and appeals, claims and encounter data analysis, and interviews with Ohio staff on demonstration implementation.

Table 9 highlights some of the quantitative measures of beneficiary experience we will monitor and evaluate using demonstration statistics and claims or encounter data analysis. See ***Section 4.2*** for a discussion of the quality, utilization, and access to care measures we plan to examine as part of the overall evaluation of impact of the Ohio demonstration on beneficiary outcomes, including for subpopulations. The draft focus group protocol and the draft stakeholder interview protocol are both discussed in this section and are available in the *Aggregate Evaluation Plan* (Walsh et al., 2013).

We will analyze our findings by subpopulation. When we can recruit sufficient numbers of individuals from the subpopulations of interest to participate in the focus groups, we will also analyze our focus group findings about beneficiary experience to determine whether differences exist by subpopulation.

Table 9
Demonstration statistics on quality, utilization, and access to care measures of beneficiary experience

Rate of auto-assignment to ICDS plans (if available)
Rate of disenrollment from the demonstration by reason[1]
Rate of beneficiaries who opt out of enrolling into demonstration
Number and type of beneficiary complaints, grievance, and appeals
Use of preventive services[1]
Nursing facility admissions and readmissions[1]
Emergency room use[1]
Hospital admission and readmission rates[1]
Follow-up care after hospital discharge[1]

ICDS = Integrated Care Delivery System.

[1] See ***Section 4.2***, for discussion of specific measures.

4.1.3 Data Sources

We will rely on five major data sources to assess beneficiary experience as shown in ***Table 8***. In this section, we describe our plan for using focus group and stakeholder interviews; results of beneficiary surveys planned by the State, CMS or other entities (e.g., CAHPS); State

demonstration data entered into the State Data Reporting System; and interviews with State demonstration staff.

4.1.3.1 Focus Groups

We will conduct four focus groups in Ohio to gain insight into how the initiative affects beneficiaries. To ensure that we capture the direct experience and observations of those served by the Ohio demonstration, focus groups will be limited to demonstration enrollees, their family members, and informal caregivers. ***Table 10*** shows our current plan for the composition and number of focus groups.

We are aware that States may consider conducting their own focus groups during demonstration implementation. If Ohio should decide to conduct focus groups, we will use Ohio's findings to inform the content of our focus groups. Preliminary topics of the focus groups we will conduct include beneficiaries' understanding of the demonstration, rights, options, and choices (e.g., plan, primary care provider); reasons beneficiaries choose to enroll and disenroll; their benefits; concerns or problems encountered; experience with care coordination; and access to primary and specialty care. Timing for conducting the focus groups will be influenced by our assessment of whether there is more to be learned about the experience of beneficiaries shortly after initial enrollment into the Ohio demonstration versus their perceptions of its effectiveness later in the Ohio demonstration. If the latter, we will conduct focus groups at least 1 year after implementation so that beneficiaries have had a substantial amount of experience with the demonstration. We will make the decision regarding timing of the focus groups in conjunction with CMS.

Table 10
Purpose and scope of State focus groups

Primary purpose	To understand beneficiary experience with the demonstration and, where possible, to identify factors and design features contributing to their experience.
Composition	Each focus group includes 8–10 individuals who may be beneficiaries or family members or caregivers representing beneficiaries. These may include but are not limited to beneficiaries with the following: • LTSS needs • physical disabilities • severe and persistent mental illness • multiple chronic conditions
Number	Four focus groups

LTSS = long-term services and supports.

We will recruit focus group participants from eligibility and enrollment files independent of input from the State. In doing so, we will identify beneficiaries reflecting a range of eligibility, clinical, and demographic characteristics enrolled in the Ohio demonstration. Our subcontractor, the Henne Group, will use a structured approach for screening potential participants and obtaining their agreement to participate. If there appear to be high rates of opting out or

disenrollment from the demonstration in Ohio, we will consider convening focus groups with beneficiaries who have chosen to opt out or disenroll to understand their decisions. We will work closely with Ohio demonstration staff to make the process for recruiting focus group members as smooth as possible for beneficiaries, such as selecting an accessible site and ensuring transportation and any needed special accommodations and supports to allow for full participation. Focus group recruitment and all focus group arrangements will be conducted with an awareness of the subpopulations of concern in Ohio. We will investigate the prevalence of non-English–speaking beneficiaries in the eligible population, and determine whether to hold any of the focus groups in languages other than English. A preliminary focus group protocol is presented in the *Aggregate Evaluation Plan* (Walsh et al., 2013). The protocol may be modified based on final decisions about focus group composition, content, and our understanding of issues raised during implementation of the Ohio demonstration.

4.1.3.2 Key Stakeholder Interviews

Our evaluation team will conduct key stakeholder interviews (consumer and advocacy groups) in Ohio, either in person as part of a scheduled site visit or by telephone, with beneficiary groups whose stakeholders are served by the Ohio demonstration. The purpose of these interviews will be to assess the level of beneficiary engagement and experience with the demonstration and its perceived impact on beneficiary outcomes. Although we will interview service providers as part of our implementation analyses, service provider perspectives will not be the source of information for assessing beneficiary experience.

Table 11 identifies potential groups in Ohio whose representatives we may wish to interview and the overall purpose of the interview. We will finalize the list of key stakeholders following discussions with demonstration staff in Ohio, a review of events and issues raised during the development of the demonstration, and the composition of enrollment by subpopulations.

A draft outline of the key stakeholder interview at baseline is presented in the *Aggregate Evaluation Plan* (Walsh et al., 2013). We will revise this draft as we obtain more information about the Ohio demonstration and the issues that arise during its planning/design phase and early implementation.

Table 11
Preliminary subpopulations and scope of key stakeholder interviews

Primary purpose	**Baseline:** Assess understanding of and satisfaction with demonstration design; expectations for the demonstration; perceived concerns and opportunities. **Throughout demonstration:** Spot improvements and issues as they emerge and assess factors facilitating and impeding positive beneficiary experience. **Final year:** Assess extent to which expectations were met; major successes and challenges; lessons learned from beneficiary's perspective.
Subpopulations	Interviews will be held with consumer and advocacy groups whose members are served by the Ohio demonstration. These may include the following: ● Advocacy organizations representing populations eligible for the demonstration, including those participating in Ohio's ICDS Stakeholder Advisory Group and the State's agencies administering programs that serve Medicare-Medicaid enrollees aged 18 or older, including the Department of Aging, the Department of Health, the Department of Mental Health, and the Department of Alcohol and Drug Addiction Services. ● Beneficiaries serving on ICDS plan local governing bodies.
Number and frequency	**Baseline**: Up to eight telephone interviews within 6 months after implementation. **Throughout demonstration**: Up to eight telephone or in-person interviews in Ohio each year to be conducted with the same individuals each time, unless additional stakeholders or topics of interest are introduced. **Final year**: Up to eight telephone or in-person interviews.

ICDS = Integrated Care Delivery System.

4.1.3.3 Beneficiary Surveys

The RTI evaluation team will not directly administer any beneficiary surveys as part of the evaluation, and we are not requiring that States administer beneficiary surveys for purposes of the evaluation. We will include relevant findings from beneficiary surveys already being conducted for this demonstration by Ohio, CMS, or other entities. We understand that Ohio Medicaid sponsors beneficiary experience surveys, such as CAHPS consumer satisfaction survey, quality of life survey, and the Ohio Family Health Survey (Ohio, 2012, p. 15). We will recommend standard questions for inclusion in surveys across all Financial Alignment Demonstrations, such as quality of life measures. Should Ohio be amenable to including these questions in its surveys, we will participate in discussions with the State and CMS (or other entities, as appropriate) regarding content and sampling issues. Topics on which we anticipate recommending common questions across all demonstration States are shown in ***Table 8***.

As part of CMS requirements for capitated model plans, ICDS plans will be required to conduct the Health Outcomes Survey (HOS) and CAHPS. The Medicare HOS and CAHPS surveys will be sampled at the ICDS plan level, allowing cross-plan and aggregate comparisons, where appropriate.

4.1.3.4 Demonstration Data

We will use data about the demonstration that we collect from Ohio during site visits, from reports and other materials developed by the State, through the State Data Reporting System, and data obtained from CMS or other entities to assess the beneficiary experience. Data of particular interest include the following:

- Complaint, appeal, and grievance data from CMS or other entities, as available.
- Disenrollment and opt-out rates.
- Information about waiting lists or lags in accessing services, which will provide useful indications of where the system lacks capacity, as a topic for discussion during site visits or focus groups.
- Rate of change in PCP assignment (if available).

The above quantitative indirect measures will be collected for all Medicare-Medicaid enrollees served under the demonstration, and will be analyzed by subpopulations.

In addition, Ohio plans to monitor quality using a selection of national measures, CMS/ State-defined process measures, and State-specified measures (MOU, 2012, pp. 76–90). To the extent relevant, we will use findings from these State-specific metrics to augment our assessment of beneficiary experience and outcomes in Ohio.

4.1.3.5 Interviews with Ohio Demonstration Staff

In addition to key stakeholder interviews conducted with consumer and advocacy groups, we will address issues of beneficiary engagement and feedback during our interviews with Ohio demonstration staff. These interviews, described in ***Section 3***, will provide another perspective on how Ohio communicates and works with beneficiaries during the design and implementation of its demonstration.

4.1.4 Analytic Methods

Our analysis will assess beneficiary experience and determine, where possible, how it is affected by financial alignment model and demonstration design features. We also want to examine whether and how beneficiary experience varies by subpopulations. The Henne Group will audio-record all focus groups, subject to approval of the group members, and the audio-recordings will be transcribed. Key stakeholder interview and focus group transcripts will be imported and analyzed using QSR NVivo 9, qualitative data analysis software, to identify emergent themes and patterns regarding beneficiary experiences during the demonstration and issues related to the evaluation research questions. A structured approach to qualitative analysis in NVivo 9 will allow us to identify themes in Ohio and compare and contrast those themes by subpopulation within and across States. Because it is implementing a capitated financial alignment model, we are particularly interested in comparing Ohio's findings with those of other States' capitated model demonstrations and in determining whether particular design features in this State's demonstration are likely to affect beneficiary experience.

Most demonstration data will be collected and tracked through the State Data Reporting System. We will also request summary statistics and reports from surveys conducted by CMS or others. Information from site visits and site-reported data beyond those described specifically in this section also are expected to inform analysis of beneficiary experience research questions. The findings will be grouped into the beneficiary experience domains defined in ***Section 4.1.2***.

The evaluation will consider indications of predemonstration beneficiary experience that may be available from other sources. The evaluation will not, however, have baseline data or comparison group results in this area. Results of beneficiary surveys, focus groups, and other approaches employed during the demonstration period will be presented in the annual and final evaluation reports along with available context to inform interpretation.

4.2 Analyses of Quality, Utilization, Access to Care, and Cost

4.2.1 Purpose

This section of the report outlines the research design, data sources, analytic methods, and key outcome variables (quality, utilization, and cost measures) on which we will focus in evaluating the Ohio demonstration. These analyses will be conducted using secondary data, including Medicare and Medicaid claims and managed care encounter data. This section addresses the following research questions:

- What impact does the Ohio demonstration have on utilization patterns in acute, long-term, and behavioral health services, overall and for beneficiary subgroups?
- What impact does the Ohio demonstration have on health care quality overall and for beneficiary subgroups?
- Does the Ohio demonstration change access to care for medical, behavioral health, long-term services and supports (LTSS) overall and for beneficiary subgroups? If so, how?
- What impact does the Ohio demonstration have on cost and is there evidence of cost savings in the State? How long did it take to observe cost savings in the State? How were these savings achieved in the State?

In this section, we discuss the approach to identifying the eligible population for Ohio and the approach for identifying comparison group beneficiaries. This section also describes the data sources, key analyses to be performed over the course of the demonstration, and the quality measures that will inform the evaluation. RTI will use both descriptive and multivariate analyses to evaluate the Ohio demonstration. Results of descriptive analyses focusing on differences across years and important subgroups on key outcome variables will be included in the Ohio quarterly reports to CMS and the State and annual reports. Multivariate analyses will be included in the final evaluation. Savings will be calculated at least twice during the demonstration—once during the demonstration and once after the end of the demonstration.

4.2.2 Approach

An appropriate research design for the evaluation must consider whether selection is a risk for bias. Potential sources of selection bias exist in the Ohio demonstration whereby the beneficiaries choosing not to enroll in the demonstration may differ from demonstration participants. First, beneficiaries may choose to opt out or disenroll from the demonstration (but will receive Medicaid services from Medicaid managed care plans). Reasons for opting out or disenrolling will vary but may be related to demonstration benefits or previous experience in

managed care. Also, beneficiaries already enrolled in the Program of All Inclusive Care for the Elderly (PACE) will not be eligible for passive enrollment into the demonstration, but may choose to disenroll from that plan and enroll in the demonstration. To limit selection bias in the evaluation of this demonstration, we will use an intent-to-treat design. This design will address potential selection issues by including the entire population of beneficiaries eligible for the Ohio demonstration, regardless of whether they enroll in the demonstration or actively participate in the care model.

Under the intent-to-treat framework, outcome analyses will include all beneficiaries eligible for the demonstration in the demonstration States, including those who opt out, participate but then disenroll, are eligible but are not contacted by the State or participating providers, and those who enroll but do not engage with the care model, and a group of similar individuals in the comparison group. This approach diminishes the potential for selection bias and highlights the effect of the demonstrations on all beneficiaries in the demonstration-eligible population. In addition, RTI will compare the characteristics of those who enroll with those who are eligible but do not enroll in the care model and conduct analyses to further explore demonstration effects on demonstration enrollees, acknowledging that interpreting such results will be difficult given likely selection bias.

4.2.2.1 Identifying Demonstration Group Members

The demonstration group for Ohio will include full-benefit Medicare-Medicaid enrollees aged 18 or older who meet the remaining demonstration eligibility criteria. To analyze quality, utilization, and costs in the predemonstration period, and throughout the demonstration period, Ohio will submit a demonstration evaluation (finder) file that includes data elements needed for RTI to correctly identify Medicare-Medicaid enrollees for linking to Medicare and Medicaid data and that includes information about whether the enrollees were eligible for or enrolled in a Financial Alignment Demonstration (***Table 12***). The file will list all of the Medicare-Medicaid eligible population for the demonstration, with additional variables in the file indicating monthly participation in the demonstration. Eligible individuals who were not enrolled in the demonstration in a given month will still be part of the evaluation under the intent-to-treat research design. In addition to indicating who was eligible and enrolled, this file will contain personal identifying information necessary for linking to Medicare and Medicaid data. RTI will notify the State about the file's design and the method and timing of transmission after the start of the demonstration.

Table 12
State demonstration evaluation (finder) file data fields

Data field	Length	Format	Valid value	Description
Medicare Beneficiary Claim Account Number (Health Insurance Claim Number [HICN])	11	CHAR	Alphanumeric	The HICN. Any Railroad Retirement Board (RRB) numbers should be converted to the HICN number prior to submission to the MDM.
MSIS number	20	CHAR	Alphanumeric	MSIS identification number.
Social security number (SSN)	9	CHAR	Numeric	Individual's SSN.
Sex	1	CHAR	Alphanumeric	Sex of beneficiary (1=male or 2=female).
Person first name	30	CHAR	Alphanumeric	The first name or given name of the beneficiary.
Person last name	40	CHAR	Alphanumeric	The last name or surname of the beneficiary.
Person birth date	8	CHAR	CCYYMMDD	The date of birth (DOB) of the beneficiary.
Person ZIP code	9	CHAR	Numeric	9-digit ZIP code.
Eligibility identification flag	1	CHAR	Numeric	Coded 0 if identified as not eligible for the demonstration, 1 if identified as eligible from administrative data, 2 if identified as eligible from non-administrative data.
Monthly enrollment indicator	1	CHAR	Numeric	Each monthly enrollment flag variable would be coded 1 if enrolled, and zero if not. Quarterly demonstration evaluation (finder) files would have 3 such data fields; annual demonstration evaluation (finder) files would have 12 such data fields.

HCBS = home and community-based services; MDM = Master Data Management; MSIS = Medicaid Statistical Information System.

4.2.2.2 Identifying a Comparison Group

The methodology described in this section reflects the plan for identifying comparison groups based on discussions between RTI and CMS and detailed in the *Aggregate Evaluation Plan* (Walsh et al., 2013). Identifying the comparison group members will entail two steps: (1) selecting the geographic area from which the comparison group will be drawn and (2) identifying the individuals who will be included in the comparison group.

Because Ohio does not intend to implement its demonstration statewide, RTI will consider an in-State comparison group. If we are unable to identify in-State comparison areas that are similar to the demonstration areas or if the in-State comparison population is not large enough, we will construct a comparison group from out-of-State Metropolitan Statistical Areas (MSAs) and determine whether there are areas within Ohio that could also be part of the comparison group. The approach for identifying an out-of-State comparison area would be the same as the process for identifying an in-State comparison group, described below.

To identify an in-State comparison area, we will use statistical distance analysis to identify potential comparison areas in Ohio that are most similar to the demonstration regions in

regard to costs, and care delivery arrangements, and policy affecting Medicare-Medicaid enrollees. The specific measures for the statistical distance analysis we will use are Medicare spending per Medicare-Medicaid enrollee, Medicaid spending per Medicare-Medicaid enrollee, nursing facility users per 65-and-over Medicaid beneficiary, HCBS users per 65-and-over Medicaid beneficiary, Personal Care users per 65-and-over Medicaid beneficiary, Medicare Advantage penetration, and Medicaid managed care penetration for full-benefit Medicare-Medicaid enrollees. The three LTSS variables capture how areas differ in the settings in which they provide these services. Variation in LTSS policy is most easily visible in the population using the most LTSS (i.e., those aged 65 and over). The relative importance of institutional care observed in that population is expected to affect such use in the population under age 65 as well. Note that any Medicare-Medicaid enrollees receiving Medicaid managed care in nondemonstration areas would be considered for the comparison group.

Once comparison areas are selected, all Medicare-Medicaid enrollees in those areas who meet the demonstration's eligibility criteria will be selected for comparison group membership based on the intent-to-treat study design. The comparison areas will be determined within the first year of demonstration implementation, in order to use the timeliest data available. The comparison group members will be determined retrospectively at the end of each demonstration year, allowing us to include information on individuals newly eligible or ineligible for the demonstration during that year. The comparison group will be refreshed annually to incorporate new entrants into the eligible population as new individuals become eligible for the demonstration over time. To ensure that the comparison group is similar to the demonstration group, we will compute propensity scores and weight comparison-group beneficiaries using the framework described in ***Section 4.2.2.4*** of this report.

If an appropriate in-State comparison group cannot be found, the same cluster analysis process used to identify an in-State comparison group will be used to identify out-of-State comparison areas. In-State and out-of-State areas may be combined to create a comparison group.

4.2.2.3 Issues/Challenges in Identifying Comparison Groups

The RTI team will make every effort to account for the following four issues/challenges when identifying and creating comparison groups.

1. **Similarities between demonstration and comparison groups:** Comparison group members are as much like demonstration group members as possible, and sufficient data are needed to identify and control for differences.

2. **Sample size:** Because an in-State comparison group is being considered, it will be important to ensure sufficient sample size for the statewide analyses and for analyses of smaller subpopulations. If the sample size is not sufficient, we will consider adding out-or-state comparison areas identified using the statistical distance analysis described above.

3. **Accounting for enrollment in other demonstrations:** Some Medicare-Medicaid enrollees may not be suitable for comparison group selection because of participation in other demonstrations or enrollment in Accountable Care Organizations. We will

work with CMS to specify these parameters and apply them to both Ohio and the comparison group.

4. **Medicaid data:** Significant delays currently exist in obtaining Medicaid data. If unaddressed, this could result in delays in formulating appropriate comparison groups. Timeliness of MSIS data submissions will need to be considered if out-of-State comparison areas are required for the evaluation.

4.2.2.4 Propensity Score Framework for Identifying Comparison Group Members

Because comparison group members may differ from the demonstration group on individual characteristics, we will compute propensity scores for the demonstration and comparison group members. The propensity score represents how well a combination of characteristics, or covariates, predicts that a beneficiary is in the demonstration group. To compute these scores for beneficiaries in the demonstration and comparison groups, we will first identify beneficiary-level and market-level characteristics to serve as covariates in the propensity-score model. Beneficiary-level characteristics may include demographics, socioeconomic, health, and disability status, and county-level characteristics may include health care market and local economic characteristics. Once the scores are computed, we will remove from the comparison group any beneficiaries with a propensity score lower than the lowest score found in the demonstration group to ensure that the comparison group is similar to the demonstration group.

The propensity scores for the comparison group will then be weighted so that the distribution of characteristics of the comparison group is similar to that of the demonstration group. By weighting comparison group members' propensity scores, the demonstration and comparison group samples will be more balanced. More detail on this process is provided in the *Aggregate Evaluation Plan* (Walsh et al., 2013).

4.2.3 Data Sources

Table 13 provides an overview of the data sources to be used in the Ohio evaluation of quality, utilization, and cost. Data sources include Medicare and Medicaid fee-for-service data, Medicare Advantage encounter data, and Medicare-Medicaid Plan encounter data. These data will be used to examine quality, utilization, and cost in the predemonstration period and during the demonstration. Data will be needed for all beneficiaries enrolled in the demonstration as well as other beneficiaries in the eligible population who do not enroll. Note that data requirements for an individual beneficiary will depend on whether they were in Medicare fee-for-service or Medicare Advantage in the pre- and post-demonstration periods.

The terms of the Ohio MOU require the State to provide timely Medicaid data through MSIS for the predemonstration and demonstration periods. Any delays in obtaining data may also delay portions of the evaluation.

The activities to identify demonstration and comparison groups and to collect and utilize claims and encounter data may be revised if modifications are made to the demonstrations or if data sources are not available as anticipated. If modifications to this evaluation plan are required, they will be documented in the annual and final evaluation reports as appropriate.

Table 13
Data sources to be used in Ohio Financial Alignment Demonstration evaluation analyses of quality, utilization, and cost

Aspect	Medicare fee-for-service data	Medicaid fee-for-service data	Encounter data[1]
Obtained from	CMS	CMS	CMS
Description and uses of data	Will be pulled from ● Part A (hospitalizations) and ● Part B (medical services). Will be used to evaluate quality of care, utilization, and cost during the demonstration. These data will be used for beneficiaries who opt out of the demonstration, have disenrolled, or do not enroll for other reasons; for predemonstration analyses of demonstration-eligible beneficiaries for the 2 years prior to the demonstration; and for comparison groups that may be in-state or out-of-state.	Medicaid claims and enrollment data will include data on patient characteristics, beneficiary utilization, and cost of services. Eligibility files will be used to examine changes in number and composition of Medicare-Medicaid enrollees. Will also need these data for beneficiaries who opt out of the demonstration, have disenrolled, or do not enroll for other reasons; for predemonstration analyses of demonstration-eligible beneficiaries for the 2 years prior to the demonstration; and for comparison groups.	Pre- and post-period beneficiary encounter data (including Medicare Advantage, ICDS, and Part D data) will contain information on ● beneficiary characteristics and diagnoses, ● provider identification/type of visit, and ● beneficiary IDs (to link to Medicare and Medicaid data files). Will be used to evaluate quality (readmissions), utilization, and cost; health; access to care; and beneficiary satisfaction. Part D data will be used to evaluate cost only. These data will also be used for beneficiaries who opt out of the demonstration, have disenrolled, or do not enroll for other reasons; for predemonstration analyses of demonstration-eligible beneficiaries for the 2 years prior to the demonstration; and for comparison groups that may be in-state or out-of state.
Sources of data	Will be pulled from the following: ● NCH Standard Analytic File ● National Claims History TAP Files ● Medicare enrollment data	Will be pulled from the following: ● MSIS (file on inpatient care, institutional, and the "other" file) ● Medicaid eligibility files	Data will be collected from the following: ● CMS ● Medicare enrollment data

(continued)

Table 13 (continued)
Data sources to be used in Ohio Financial Alignment Demonstration evaluation analyses of quality, utilization, and cost

Aspect	Medicare fee-for-service data	Medicaid fee-for-service data	Encounter data[1]
Time frame of data	Baseline file = 2 years prior to the demonstration period (NCH Standard Analytic File). Evaluation file = all demonstration years (NCH TAP Files).	Baseline file = 2 years prior to the demonstration period. Evaluation file = all demonstration years.	Baseline file = Medicare Advantage plans submit encounter data to CMS as of January 1, 2012. RTI will determine to what extent these data can be used in the baseline file. Evaluation file = Medicare Advantage and ICDS plans are required to submit encounter data to CMS for all demonstration years.
Potential concerns	—	Expect significant time delay for all Medicaid data.	CMS will provide the project team with data from ICDS plans under new Medicare Advantage requirements. Any lags in data availability are unknown at this time.

— = No data; ICDS = Integrated Care Delivery System; MSIS = Medicaid Statistical Information System; NCH = National Claims History; TAP = monthly Medicare claims files.

[1] Encounter data from Medicare Advantage (MA) or PACE plans in the pre-period are needed to evaluate demonstration impact for beneficiaries who previously were enrolled in Medicare Advantage or PACE plans but who enroll in the demonstration. There may also be movement between Medicare Advantage or PACE plans and the demonstration throughout implementation, which we will need to take into account using Medicare Advantage or PACE encounter data during the implementation period.

Notes on Data Access: CMS data contain individually identifiable data that are protected under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. CMS, however, makes data available for certain research purposes provided that specified criteria are met. RTI has obtained the necessary Data Use Agreement (DUA) with CMS to use CMS data. A listing of required documentation for requesting CMS identifiable data files such as Medicare and MSIS is provided at http://www.resdac.umn.edu/medicare/requesting_data.asp.

4.3 Analyses

The analyses of quantitative data on quality, utilization, and cost measures in the Ohio evaluation will consist of the following:

1. a monitoring analysis to track quarterly changes in selected quality, utilization, and cost measures over the course of the Ohio demonstration (as data are available) ;
2. a descriptive analysis of quality, utilization, and cost measures for annual reports with means and comparisons for subgroups of interest, including comparison group results; and
3. multivariate difference-in-differences analyses of quality, utilization, and cost measures using an in-State comparison group or a combination of in-State and out-of-State areas if necessary.

At least one multivariate regression-based savings analysis will be calculated during the demonstration period, most likely using 2 years of demonstration data. A second savings analysis will be included in the final evaluation.

The approach to each of these analyses is outlined below in ***Table 14,*** and more detail is provided in the *Aggregate Evaluation Design Report* (Walsh et al, 2013). The activities for the analyses may be revised if modifications are made to the demonstrations or if data sources are not available as anticipated. If modifications to this evaluation plan are required, they will be documented in the annual and final evaluation reports as appropriate.

4.3.1 Monitoring Analysis

Data from Medicare FFS, Medicare Advantage encounter data, ICDS plan encounter data, MSIS data files, and other data provided by Ohio via the State Data Reporting System will be analyzed quarterly to calculate means, counts, and proportions on selected quality, utilization, and cost measures common across States, depending on data availability. Examples of measures that may be included in these quarterly reports to CMS include rates of inpatient admissions, emergency room visits, long-term nursing facility admissions, cost per member per month, and all-cause hospital readmission and mortality. We will present the current value for each quarter and the predemonstration period value for each outcome to look at trends over time.

The goal of these analyses is to monitor and track changes in quality, utilization, and costs. Though quarterly analyses will not be multivariate or include comparison group data, these monitoring data will provide valuable, ongoing information on trends occurring during the demonstration period. Various inpatient and emergency room measures that can be reported are described in more detail in the section on quality measures.

Table 14
Quantitative Analyses to be performed for the Ohio demonstration

Aspect	Monitoring analysis	Descriptive analysis	Multivariate analyses
Purpose	Track quarterly changes in selected quality, utilization, and cost measures over the course of the demonstration.	Provide estimates of quality, utilization, and cost measures on an annual basis.	Measure changes in quality, utilization, and cost measures as a result of the demonstration.
Description of analysis	Comparison of current value and values over time to the baseline period value for each outcome.	Comparison of the baseline period with each demonstration year for demonstration and comparison groups.	Difference-in-differences analyses using demonstration and comparison groups.
Reporting frequency	Quarterly to CMS and the State	Annually	Once, in the final evaluation except for costs which will also be calculated (at least) once prior to the final evaluation.

NOTE: The reports to be submitted to CMS will include the qualitative data described earlier in this report in addition to the quantitative data outlined here.

4.3.2 Descriptive Analysis of Quality, Utilization, and Cost Measures

We will conduct a descriptive analysis of quality, utilization, and cost measures for the Ohio demonstration annually for each performance period that include means, counts, proportions for the demonstration and comparison groups. This analysis will focus on estimates for a broad range of quality, utilization, and cost measures, as well as changes in these measures across years or subgroups of interest within each year. The results of these analyses will be presented in the annual evaluation reports. The sections below outline the measures that will be included.

To perform this analysis, we will develop separate (unlinked) encounter, Medicare, and Medicaid beneficiary-level analytic files annually to measure quality, utilization, and cost. Though the Medicare, Medicaid, and encounter data will not be linked, the unlinked, beneficiary-level files will still allow for an understanding of trends in a subset of quality, utilization, and cost measures. The analytic files will include data from the predemonstration period and for each demonstration year. Because of the longer expected time lags in the availability of Medicaid data, Medicare fee-for-service data and ICDS encounter data may be available sooner than Medicaid fee-for-service data. Therefore, we expect that the first annual report will include predemonstration Medicare and Medicaid fee-for-service data, and Medicare fee-for-service, Medicare Advantage, and ICDS encounter data for the demonstration period. Medicaid fee-for-service data will be incorporated into later reports as the data become available.

Consistent with the intent-to-treat approach, all individuals eligible to participate in the demonstration will be included in the analysis, regardless of whether they opt out of the demonstration or disenroll, or actively engage in the care model. Data will be developed for demonstration and comparison group beneficiaries for a 2-year predemonstration period and for each of the years of the demonstration. The starting date for Ohio will be based on the State's

implementation date and, therefore, may represent a "performance period," not necessarily a calendar year. For those beneficiaries with shorter enrollment periods, because of beneficiary death or change of residence, for example, the analysis will weight their experience by months of enrollment within a performance period.

We will measure predemonstration and annual utilization rates and costs of Medicare- and Medicaid-covered services together, where appropriate, to look at trends in the type and level of service use during the State demonstrations. We will calculate average use rates at predemonstration and for each demonstration period. Use rates of Medicare- and Medicaid-covered services will be stratified by hierarchical condition category (HCC) scores, which are derived from models predicting annual Medicare spending based on claim-based diagnoses in a prior year of claims where higher scores are predictive of higher spending, health status measures, or similar measures. We will adjust for hospitalizations in the prior year using categorical HCC scores or similar. Chi-square and t-tests will be used to test for significant differences in use across years and between subpopulations such as Medicare-Medicaid enrollees using behavioral health services and those referred for long-term care services.

4.3.3 Multivariate Analyses of Quality, Utilization, and Cost Measures

In the final year of the evaluation, we will use data collected for the eligible population in Ohio and data for the selected comparison group that will have been adjusted using propensity-score weighting methods to analyze the effect of the demonstration using a difference-in-differences method. This method uses both pre- and post-period data for both the demonstration and comparison groups to estimate effects. This method will be applied to these data for each quality, utilization, and cost outcome described in the next section for the final evaluation. The analytic approaches are described in greater detail in the *Aggregate Evaluation Plan* (Walsh et al., 2013). In addition, multivariate regression-adjusted estimates of cost effects (only) will be performed at an intermediate point of the evaluation, using data after 2 years of implementation.

4.3.4 Subpopulation Analyses

For subpopulations of focus in the Ohio demonstration, we will evaluate the impact of the demonstration on quality, utilization, and access to care for medical, LTSS, and behavioral health services, and also examine qualitative data gathered through interviews, focus groups, and surveys. RTI will compare the characteristics of those who enroll with those who are eligible but do not enroll in the care model and conduct analyses to further explore demonstration effects on demonstration enrollees, acknowledging that selection bias must be taken into account in interpreting the results.

Descriptive analyses for annual reports will present results on selected measures stratified by subpopulations (e.g., those using and not using behavioral health services, LTSS). Multivariate analyses performed for the final evaluation will account for differential effects for subpopulations in specification testing by using dummy variables for each of the specific subpopulations of interest one at a time so that the analyses can suggest whether quality, utilization, and cost are higher or lower for each of these groups.

4.4 Utilization and Access to Care

Medicare, Medicaid, and ICDS encounter data will be used to evaluate changes in the levels and types of services used, ranging along a continuum from institutional care to care provided at home (***Table 15***). Note that ***Table 15*** indicates the sources of data for these analyses during the demonstration, given that the analyses will include beneficiaries who enroll in the demonstration as well as those who are part of the population eligible for the demonstration, but do not enroll in the demonstration.

Table 15
Service categories and associated data sources for reporting utilization measures

Service type	Encounter data (Medicare Advantage, ICDS, and Medicaid MCOs)	Medicaid only (FFS)	Medicare and Medicaid (FFS)
Inpatient	X	—	X
Emergency room	X	—	X
Nursing facility (short rehabilitation stay)	X	—	—
Nursing facility (long-term stay)	X	X	—
Other facility-based[1]	X	—	X
Outpatient[2]	X	—	X
Outpatient behavioral health (mental and substance use)	X	X	—
Home health	X	—	X
HCBS (PAS, waiver services)	X	X	—
Dental	X	X	—

— = not available; FFS = fee for service; HCBS = home and community-based services; ICDS = Integrated Care Delivery System; PAS = personal assistance services.

[1] Includes long-term care hospital, rehabilitation hospital, State mental health facility stays.

[2] Includes visits to physician offices, hospital outpatient departments, rehabilitation agencies.

We anticipate being able to develop traditional utilization measures for each of the service classes in ***Table 15*** (e.g., various inpatient use rates based on diagnoses of interest); however, as of this writing, the data that demonstration ICDS plans will be required to submit have not been finalized.

4.5 Quality of Care

Across all States, we will evaluate a core quality measure set for monitoring and evaluation purposes. There are multiple data sources for quality measures: claims and encounter data, which will be obtained and analyzed by the RTI team for evaluation measures listed in ***Table 16***, and information collected by the State, CMS, or others and provided in aggregate to the RTI team for inclusion in reports. The latter may include HEDIS measures collected as part of health plan performance, other data Ohio requires its ICDS plans to report, and any

beneficiary survey data collected by Ohio, CMS, or other entities (e.g., CAHPS). CMS and Ohio have also identified a set of quality measures that will determine the amount of quality withhold payments (i.e., ICDS plans must meet quality standards to earn back a withheld portion of their capitated payments). The quality withhold measures, listed in the Ohio MOU, include some measures noted in this report, as well as additional measures. RTI expects to have access to the aggregated results of these additional measures and will include them in the evaluation as feasible and appropriate, understanding that these data are not available for the predemonstration period or for the comparison group.

RTI and CMS have developed the core set of evaluation measures for use across State demonstrations; the evaluation will also include a few measures specific to Ohio.

Table 16 provides a working list of the core quality measures for the evaluation of the Financial Alignment Initiative. The table specifies the measure, the source of data for the measure, whether the measure is intended to produce impact estimates, as well as more detailed definition and specification of the numerator and denominator for the measure. These measures will be supplemented by additional evaluation measures appropriate to the Ohio demonstration. We will finalize State-specific quality measures within the first 6 months of implementation.

Many of the measures in ***Table 16*** are established HEDIS measures that demonstration plans are required to report. The National Committee for Quality Assurance (NCQA) definitions are established and standardized. Given that these data will not be available for those who opt out or disenroll or for comparison populations, we will collect and present the results for each relevant demonstration period.

Finally, the evaluation will analyze subgroups of interest and look at measures that might be particularly relevant to them (e.g., measures that might be specific to people with developmental disabilities, behavioral health conditions). We will continue to work with CMS and the State to identify measures relevant to Ohio and will work to develop specifications for these measures.

Table 16
Evaluation quality measures: Detailed definitions, use, and specifications

Measure concept (specific measure)	Data sources and responsibility for data collection	Domain (prevention, care coordination, beneficiary experience)	Will evaluation produce impact estimates?[1]	Definition (link to documentation if available)	Numerator/denominator description
All-cause readmission 30-day all-cause risk-standardized readmission rate	Claims/encounter RTI will acquire and analyze	Care coordination	Yes	Risk-adjusted percentage of demonstration-eligible Medicare-Medicaid enrollees who were readmitted to a hospital within 30 days following discharge from the hospital for the index admission (https://www.cms.gov/sharedsavingsprogram/Downloads/ACO_QualityMeasures.pdf).	Numerator: Risk-adjusted readmissions among demonstration-eligible Medicare-Medicaid enrollees at a non-Federal, short-stay, acute-care or critical access hospital, within 30 days of discharge from the index admission included in the denominator, and excluding planned readmissions. Denominator: All hospitalizations among demonstration-eligible Medicare-Medicaid enrollees not related to medical treatment of cancer, primary psychiatric disease, or rehabilitation care, fitting of prostheses, and adjustment devices for beneficiaries at non-Federal, short-stay acute-care or critical access hospitals, where the beneficiary was continuously enrolled in Medicare and Medicaid for at least 1 month after discharge, was not discharged to another acute-care hospital, was not discharged against medical advice, and was alive upon discharge and for 30 days post-discharge.
Immunizations Influenza immunization	Claims/encounter RTI will acquire and analyze	Prevention	Yes	Percentage of demonstration-eligible Medicare-Medicaid enrollees seen for a visit between October 1 and March 31 of the 1-year measurement period who received an influenza immunization OR who reported previous receipt of an influenza immunization (https://www.cms.gov/sharedsavingsprogram/Downloads/ACO_QualityMeasures.pdf).	Numerator: Demonstration-eligible Medicare-Medicaid enrollees who have received an influenza immunization OR who reported previous receipt of influenza immunization. Denominator: Demonstration-eligible Medicare-Medicaid enrollees seen for a visit between October 1 and March 31 (flu season), with some exclusions allowed.

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Table 16 (continued)
Evaluation measures: Detailed definitions, use, and specifications

Measure concept (specific measure)	Data sources and responsibility for data collection	Domain (prevention, care coordination, beneficiary experience)	Will evaluation produce impact estimates?[1]	Definition (link to documentation if available)	Numerator/denominator description
Immunizations (cont'd) Pneumococcal vaccination for patients 65 years and older	Claims/encounter RTI will acquire and analyze	Prevention	Yes	Percentage of demonstration-eligible patients aged 65 years and older who have ever received a pneumococcal vaccine.	Numerator: Demonstration-eligible Medicare-Medicaid enrollees age 65 and over who have ever received a pneumococcal vaccination. Denominator: All demonstration-eligible Medicare-Medicaid enrollees aged 65 years and older, excluding those with documented reason for not having one.
Ambulatory care-sensitive condition admission Ambulatory care sensitive condition admissions—overall composite (AHRQ PQI # 90)	Claims/encounter RTI will acquire and analyze	Prevention, care coordination	Yes	Combination using 12 individual ACSC diagnoses for chronic and acute conditions. For technical specifications of each diagnosis, see http://www.qualityindicators.ahrq.gov/Modules/PQI_TechSpec.aspx.	Numerator: Total number of acute-care hospitalizations for 12 ambulatory care-sensitive conditions among demonstration-eligible Medicare-Medicaid enrollees, aged 18 or older. Conditions include diabetes—short-term complications; diabetes—long-term complications; COPD; hypertension; CHF; dehydration; bacterial pneumonia; UTI; angina without procedure; uncontrolled diabetes; adult asthma; lower extremity amputations among diabetics. Denominator: Demonstration-eligible Medicare-Medicaid enrollees, aged 18 or older.
Ambulatory care-sensitive condition admissions—chronic composite (AHRQ PQI # 92)	Claims/encounter RTI will acquire and analyze	Prevention, care coordination	Yes	Combination using 9 individual ACSC diagnoses for chronic diseases. For technical specifications of each diagnosis, see http://www.qualityindicators.ahrq.gov/Modules/PQI_TechSpec.aspx.	Numerator: Total number of acute-care hospitalizations for 9 ambulatory care sensitive chronic conditions among demonstration-eligible Medicare-Medicaid enrollees, aged 18 or older. Conditions include diabetes—short-term complications; diabetes—long-term complications; COPD; hypertension; CHF; angina w/o procedure; uncontrolled diabetes; adult asthma; lower-extremity amputations among diabetics). Denominator: demonstration-eligible Medicare-Medicaid enrollees, aged 18 or older.

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Table 16 (continued)
Evaluation measures: Detailed definitions, use, and specifications

Measure concept (specific measure)	Data sources and responsibility for data collection	Domain (prevention, care coordination, beneficiary experience)	Will evaluation produce impact estimates?[1]	Definition (link to documentation if available)	Numerator/denominator description
Admissions with primary diagnosis of a severe and persistent mental illness or substance use disorder	Claims/encounter RTI will acquire and analyze	Prevention, care coordination	Yes	Percentage of demonstration-eligible Medicare-Medicaid enrollees with a primary diagnosis of a severe and persistent mental illness or substance use disorder who are hospitalized	Numerator: Total number of acute-care hospitalizations among demonstration-eligible Medicare-Medicaid enrollees, aged 18 or older with a primary diagnosis of a severe and persistent mental illness or substance use who are hospitalized. Denominator: Demonstration-eligible Medicare-Medicaid enrollees, aged 18 or older.
Avoidable emergency department visits Preventable/ avoidable and primary care treatable ED visits	Claims/encounter RTI will acquire and analyze	Prevention, care coordination	Yes	Based on lists of diagnoses developed by researchers at the New York University Center for Health and Public Service Research, this measure calculates the rate of ED use for conditions that are either preventable/avoidable, or treatable in a primary care setting (http://wagner.nyu.edu/faculty/billings/nyued-background).	Numerator: Total number of ED visits with principal diagnoses defined in the NYU algorithm among demonstration-eligible Medicare-Medicaid enrollees. Denominator: Demonstration-eligible Medicare-Medicaid enrollees.
Emergency department visits ED visits excluding those that result in death or hospital admission	Claims/encounter RTI will acquire and analyze	Prevention, care coordination	Yes	Percentage of demonstration-eligible Medicare-Medicaid enrollees with an emergency department visit.	Numerator: Total number of ED visits among demonstration-eligible Medicare-Medicaid enrollees excluding those that result in death or hospital admission. Denominator: Demonstration-eligible Medicare-Medicaid enrollees.

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Table 16 (continued)
Evaluation measures: Detailed definitions, use, and specifications

Measure concept (specific measure)	Data sources and responsibility for data collection	Domain (prevention, care coordination, beneficiary experience)	Will evaluation produce impact estimates?[1]	Definition (link to documentation if available)	Numerator/denominator description
Follow-up after mental health hospitalization Follow-up after hospitalization for mental illness	Claims/encounter RTI will acquire and analyze	Care coordination	Yes	Percentage of discharges for demonstration-eligible Medicare-Medicaid enrollees who were hospitalized for selected mental health disorders and who had an outpatient visit, an intensive outpatient encounter, or partial hospitalization with a mental health practitioner. Two rates are reported: (1) The percentage of members who received follow-up within 30 days of discharge; (2) The percentage of members who received follow-up within 7 days of discharge (http://www.qualityforum.org/QPS/).	Numerator: Rate 1: (Among demonstration-eligible Medicare-Medicaid enrollees) an outpatient visit, intensive outpatient encounter, or partial hospitalization with a mental health practitioner within 30 days after discharge. Include outpatient visits, intensive outpatient encounters, or partial hospitalizations that occur on the date of discharge; Rate 2: (Among demonstration-eligible Medicare-Medicaid enrollees) an outpatient visit, intensive outpatient encounter, or partial hospitalization with a mental health practitioner within 7 days after discharge. Include outpatient visits, intensive outpatient encounters, or partial hospitalizations that occur on the date of discharge. Denominator: demonstration-eligible Medicare-Medicaid enrollees who were discharged alive from an acute inpatient setting (including acute-care psychiatric facilities) in the measurement year. The denominator for this measure is based on discharges, not members. Include all discharges for members who have more than one discharge in the measurement year.
Fall prevention Screening for fall risk	Claims/ encounter RTI will acquire and analyze	Prevention, care coordination	Yes	Percentage of demonstration-eligible Medicare-Medicaid enrollees aged 65 years and older who were screened for future fall risk at least once within 12 months	Numerator: Demonstration-eligible Medicare-Medicaid enrollees who were screened for future fall risk at least once within 12 months. Denominator: All demonstration-eligible Medicare-Medicaid enrollees 65 years or older.

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Table 16 (continued)
Evaluation measures: Detailed definitions, use, and specifications

Measure concept (specific measure)	Data sources and responsibility for data collection	Domain (prevention, care coordination, beneficiary experience)	Will evaluation produce impact estimates?[1]	Definition (link to documentation if available)	Numerator/denominator description
Cardiac rehabilitation Cardiac rehabilitation following hospitalization for AMI, angina CABG, PCI, CVA	Claims/encounter RTI will acquire and analyze	Care coordination	Yes	Percentage of demonstration-eligible beneficiaries evaluated in an outpatient setting who within the past 12 months have experienced AMI, CABG surgery, PCI, CVA, or cardiac transplantation, or who have CVA and have not already participated in an early outpatient CR program for the qualifying event/ diagnosis who were referred to a CR program.	Numerator: Number of demonstration-eligible Medicare-Medicaid enrollees in an outpatient practice who have had a qualifying event/diagnosis in the previous 12 months who have been referred to an outpatient cardiac rehabilitation/secondary prevention program. Denominator: Number of demonstration-eligible Medicare-Medicaid enrollees in an outpatient clinical practice who have had a qualifying cardiovascular event in the previous 12 months, who do not meet any of the exclusion criteria, and who have not participated in an outpatient cardiac rehabilitation program since the cardiovascular event.
Pressure ulcers Percent of high-risk residents with pressure ulcers (long stay)	MDS RTI will acquire and analyze	Prevention, care coordination	Yes	Percentage of all demonstration-eligible long-stay residents in a nursing facility with an annual, quarterly, significant change, or significant correction MDS assessment during the selected quarter (3-month period) who were identified as high risk and who have one or more Stage 2–4 pressure ulcer(s).	Numerators: Number of demonstration-eligible Medicare-Medicaid enrollees who are long-stay nursing facility residents who have been assessed with annual, quarterly, significant change, or significant correction MDS 3.0 assessments during the selected time window and who are defined as high risk with one or more Stage 2–4 pressure ulcer(s). Denominators: Number of demonstration-eligible Medicare-Medicaid enrollees who are long-stay residents who received an annual, quarterly, or significant change or significant correction assessment during the target quarter and who did not meet exclusion criteria.

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Table 16 (continued)
Evaluation measures: Detailed definitions, use, and specifications

Measure concept (specific measure)	Data sources and responsibility for data collection	Domain (prevention, care coordination, beneficiary experience)	Will evaluation produce impact estimates?[1]	Definition (link to documentation if available)	Numerator/denominator description
Treatment of alcohol and substance use disorders Initiation and engagement of alcohol and other drug dependent treatment	Claims/encounter RTI will acquire and analyze	Care coordination	Yes	The percentage of demonstration-eligible Medicare-Medicaid enrollees with a new episode of alcohol or other drug (AOD) dependence who received the following: a. Initiation of AOD Treatment. The percentage who initiate treatment through an inpatient AOD admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of the diagnosis. b. Engagement of AOD Treatment. The percentage who initiated treatment and who had two or more additional services with a diagnosis of AOD within 30 days of the initiation visit. (http://www.qualityforum.org/QPS/)	Numerator: Among demonstration-eligible Medicare-Medicaid enrollees (a) Initiation: AOD treatment through an inpatient admission, outpatient visit, intensive outpatient encounter or partial hospitalization within 14 days of diagnosis; (b) Engagement: AOD treatment and two or more inpatient admissions, outpatient visits, intensive outpatient encounters or partial hospitalizations with any AOD diagnosis within 30 days after the date of the Initiation encounter (inclusive). Multiple engagement visits may occur on the same day, but they must be with different providers in order to be counted. Do not count engagement encounters that include detoxification codes (including inpatient detoxification). Denominator: Demonstration-eligible Medicare-Medicaid enrollees age 13 years and older who were diagnosed with a new episode of alcohol and drug dependency during the intake period of January 1–November 15 of the measurement year. EXCLUSIONS: Exclude those who had a claim/encounter with a diagnosis of AOD during the 60 days before the IESD. For an inpatient IESD, use the admission date to determine the Negative Diagnosis History. For an ED visit that results in an inpatient stay, use the ED date of service.
Depression screening and follow-up Screening for clinical depression and follow-up	Claims/encounter RTI will acquire and analyze	Prevention, care coordination	Yes	Percentage of patients aged 18 and older screened for clinical depression using an age-appropriate standardized tool AND follow-up plan documented (http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2014_eCQM_EP_June2013.zip).	Numerator: Demonstration-eligible Medicare-Medicaid enrollees whose screening for clinical depression using an age-appropriate standardized tool AND follow-up plan is documented. Denominator: All demonstration-eligible Medicare-Medicaid enrollees 18 years and older with certain exceptions (see source for the list).

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Table 16 (continued)
Evaluation measures: Detailed definitions, use, and specifications

Measure concept (specific measure)	Data sources and responsibility for data collection	Domain (prevention, care coordination, beneficiary experience)	Will evaluation produce impact estimates?[1]	Definition (link to documentation if available)	Numerator/denominator description
Blood pressure control Controlling high blood pressure	Medical records (HEDIS EOC035)	Prevention, care coordination	No	Percentage of members aged 18–85 who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90mm Hg) during the measurement year (http://www.qualityforum.org/QPS).	Numerator: Number of demonstration participants in the denominator whose most recent, representative BP is adequately controlled during the measurement year. For a member's BP to be controlled, both the systolic and diastolic BP must be <140/90mm Hg. Denominator: Demonstration participants with hypertension. A patient is considered hypertensive if there is at least one outpatient encounter with a diagnosis of HTN during the first 6 months of the measurement year.
Weight screening and follow-up Adult BMI assessment	Medical records (HEDIS EOC110)	Prevention	No	Percentage of patients aged 18–74 years of age who had an outpatient visit and who had their BMI documented during the measurement year or the year prior to measurement.	Numerator: BMI documented during the measurement year, or the year prior. Denominator: Demonstration-eligible Medicare-Medicaid enrollees 18–74 who had an outpatient visit.
Breast cancer screening	Medical records (HEDIS 0003)	Prevention	No	Percentage of women 40–69 years of age and participating in demonstration who had a mammogram to screen for breast cancer.	Numerator: Number of women 40–69 receiving mammogram in year. Denominator: Number of women 40–69 enrolled in demonstration.

(continued)

Table 16 (continued)
Evaluation measures: Detailed definitions, use, and specifications

Measure concept (specific measure)	Data sources and responsibility for data collection	Domain (prevention, care coordination, beneficiary experience)	Will evaluation produce impact estimates?[1]	Definition (link to documentation if available)	Numerator/denominator description
Antidepressant medication management	Medical records (HEDIS EOC030)	Care coordination	No	Percentage of members 18+ who were diagnosed with a new episode of major depression and treated with antidepressant medication, and who remained on an antidepressant medication treatment.	Numerator: Two rates are reported. (1) Effective acute phase treatment—newly diagnosed and treated demonstration participants who remain on antidepressant medication for at least 84 days. (2) Effective continuation phase treatment—newly diagnosed and treated demonstration participants who remained on antidepressant medication for at least 180 days. Denominator: Newly diagnosed and treated demonstration participants over age 18.
Diabetes care Comprehensive diabetes care: selected components—HbA1c control, LDL-C control, retinal eye exam	Medical records (HEDIS EOC020)	Prevention/care coordination	No	Percentage of demonstration participants 18–75 years of age with diabetes (type 1 and type 2) who had each of the following: HbA1c control, LDL-C control, and retinal eye exam.	Numerator: Number of these who had HbA1c control or LDL-C control, or retinal eye exam in year. Denominator: Demonstration participants 18–75 with type 1 or type 2 diabetes.

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Table 16 (continued)
Evaluation measures: Detailed definitions, use, and specifications

Measure concept (specific measure)	Data sources and responsibility for data collection	Domain (prevention, care coordination, beneficiary experience)	Will evaluation produce impact estimates?[1]	Definition (link to documentation if available)	Numerator/denominator description
Medication management Annual monitoring for patients on persistent medications	Medical records (HEDIS EOC075)	Care coordination	No	Percentage who received at least 180 treatment days of ambulatory medication therapy for a select therapeutic agent during the measurement year and at least one therapeutic monitoring event for the therapeutic agent in the measurement year. Agents measured: (1) ACE inhibitors or ARB, (2) digoxin, (3) diuretics, (4) anticonvulsants.	Numerator: Number with at least 180 days of treatment AND a monitoring event in the measurement year. Combined rate is sum of 4 numerators divided by sum of 4 denominators. Denominator: Demonstration participants with at least 180 days of treatment in the year for a particular agent.

ACE = angiotensin-converting-enzyme; ARB = Angiotensin II receptor blockers; ACSC = ambulatory care sensitive conditions; AMI = acute myocardial infarction; AOD = alcohol or other drug; BMI = body mass index; BP = blood pressure; CABG = coronary artery bypass graft; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; CVA= cerebrovascular accident; ED = emergency department; HbA1c = Hemoglobin A1c; HEDIS = Healthcare Effectiveness Data and Information Set; HTN = hypertension; IESD = Index Episode Start Date; LDL-C = low-density-lipoprotein cholesterol (bad cholesterol); MDS = minimum data set; PCI = percutaneous coronary intervention; UTI = urinary tract infection.

[1] Impact estimates will be produced only for measures where data can also be obtained for the comparison group. Measures for which data are not expected to be available in the comparison group will be tracked only within the demonstration to measures changes over time.

NOTE: Definitions, use, and specifications are as of 1/3/14.

4.6 Cost

To determine annual total costs (overall and by payer), we will aggregate the Medicare and Medicaid per member per month (PMPM) payments paid to the ICDS plans and the costs for the eligible population who are not enrolled in the demonstration per the intent-to-treat evaluation design. This approach will help us to detect overall cost impact and eliminate the effects of potential selection bias among beneficiaries who participate in the demonstration and those who opt out or disenroll. We will include Part D PMPM and any PMPM reconciliation data provided by CMS in the final assessment of cost impact to ensure that all data are available.

We will analyze cost data for the service types shown in ***Table 14*** in the previous section on utilization with the addition of prescription drug costs. We will present results for important subgroups, and in more detail to better understand their demonstration experience. We will also create a high-cost-user category and track costs of this group over time. To do this, we will measure the percentage of beneficiaries defined as high cost in Year 1 (e.g., those beneficiaries in the top 10 percent of costs). In subsequent years we will look at the percentage of beneficiaries above the Year 1 threshold to learn more about potential success in managing the costs of high-cost beneficiaries as a result of the demonstration.

We will also evaluate cost savings for capitated model demonstrations twice during the demonstration using a regression-based approach and the comparison group described in ***Section 4.2.2*** of this report. The methodology for evaluating cost savings for capitated model demonstrations is currently under development and will be reviewed and approved by Office of the Actuary. If data are available, we will also estimate cost savings accruing to the Medicare and Medicaid programs separately.

4.7 Analytic Challenges

Obtaining Medicaid fee-for-service data for the predemonstration and demonstration periods and ICDS encounter data for the demonstration period will be critical for the evaluation. It will be important for Ohio to submit Medicaid fee-for-service data in a timely manner. It will also be important for CMS to continue to work with other States that may serve as comparison groups to update and maintain their MSIS/t-MSIS submissions. Additionally, in order to identify costs by service category, encounter data need to include pricing information. ICDS encounter data are in the process of being finalized, so RTI will continue to work closely with CMS to understand the contents of the data provided by plans and how best these data can be utilized by the evaluation.

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