DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

July 28, 2016

Joseph Moser
Medicaid Director
Indiana Family and Social Services Administration
402 W. Washington St., Room W461
Indianapolis, IN 46204

Dear Mr. Moser:

This letter is to inform you that the Centers for Medicare & Medicaid Services (CMS) has approved a five-year extension of Indiana's section 1115 demonstration entitled, "End Stage Renal Disease" (Project Number 11-W- 00237/5), formerly entitled the "Healthy Indiana Plan (HIP) 1.0." The demonstration is approved in accordance with section 1115(a) of the Social Security Act (the Act) and is effective on the date of this signed approval. Through this demonstration, the state will provide Medicare-enrolled individuals who are otherwise ineligible for Medicaid with End Stage Renal Disease (ESRD) with supplemental wrap-around coverage, including supplemental coverage for kidney transplant services.

CMS' approval of the ESRD section 1115(a) demonstration extension is subject to the limitations specified in the approved expenditure authorities and the state's continued compliance with the enclosed special terms and conditions (STCs) that define the nature, character, and extent of federal involvement in this demonstration project.

This approval is subject to CMS receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter. A copy of the STCs and expenditure authorities are enclosed.

Your project officer for this demonstration is Ms. Patricia Hansen. She is available to answer any questions concerning this section 1115(a) demonstration extension. Ms. Hansen's contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid & CHIP Services
Mail Stop: S2-03-14
7500 Security Boulevard
Baltimore, MD 21244-1850
Telephone: 410-786-4252
E-mail: patricia.hansen1@cms.hhs.gov

Official communications regarding program matters should be sent simultaneously to Ms. Hansen and to Ms. Ruth Hughes, Associate Regional Administrator for the Division of Medicaid &

Children's Health in the Chicago Regional Office. Ms. Hughes's contact information is as follows:

Ms. Ruth Hughes
Associate Regional Administrator
Division of Medicaid and Children Health Operations
233 North Michigan Avenue, Suite 600
Chicago, IL 60601
Email: Ruth.Hughes@cms.hhs.gov

If you have additional questions, please contact Mr. Eliot Fishman, Director, State Demonstrations Group, Center for Medicaid & CHIP Services at (410) 786-9686.

Sincerely,

/s/

Vikki Wachino
Director

Enclosures

cc: Ruth Hughes, Associate Regional Administrator, CMS Chicago Regional Office
Tannisse Joyce, CMS Chicago Regional Office

CENTERS FOR MEDICARE AND MEDICAID SERVICES
EXPENDITURE AUTHORITY

NUMBER: **No. 11-W-00237/5**

TITLE: **End Stage Renal Disease (ESRD) Medicaid Section 1115 Demonstration**

AWARDEE: **Indiana Family and Social Services Administration**

Under the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by the state for the items identified below, which are not otherwise included as expenditures under section 1903, shall, for the period of this demonstration, be regarded as expenditures under the state's Medicaid title XIX state plan.

The following expenditure authorities shall enable Indiana to implement the End Stage Renal Disease (ESRD) Medicaid section 1115 demonstration. These expenditure authorities promote the objectives of title XIX by increasing overall coverage of low-income individuals with a diagnosis of ESRD in the state and ensuring access to comprehensive coverage for low-income individuals who have a diagnosis of ESRD and primary coverage through Medicare.

1. **Demonstration Population 1:** Expenditures for health care related costs for individuals that were enrolled in Medicaid spend down as of May 31, 2014, continue to meet the requirements for spend down eligibility that were in effect on that date, have Medicare, meet resource requirements limit of $1,500 for an individual and $2,250 for a couple, over 150 percent of the federal poverty level (FPL), have a diagnosis of ESRD, are not institutionalized, and meet all other Medicaid non-financial eligibility criteria, but are not otherwise eligible for Medicaid.

2. **Demonstration Population 2:** Expenditures for health care related costs for individuals have incomes between 150 and 300 percent of the FPL, have Medicare, are diagnosed with ESRD, have resources less than $1,500 for an individuals and $2,250 for a couple, are not institutionalized, and meet all other Medicaid non-financial eligibility criteria, but are not otherwise eligible for Medicaid or Demonstration Population 1.

CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS

NUMBER: **11-W-00303/5**

TITLE: **End Stage Renal Disease**

AWARDEE: **Indiana Family and Social Services Administration**

I. PREFACE

The following are the Special Terms and Conditions (STCs) for Indiana's End Stage Renal Disease (ESRD) section 1115(a) Medicaid demonstration (hereinafter referred to as "demonstration"). The parties to this agreement are the Indiana Family and Social Services Administration (hereinafter referred to as "state") and the Centers for Medicare & Medicaid Services (CMS). These STCs set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's obligations to CMS during the life of the demonstration. The STCs are effective July 28, 2016 unless otherwise specified. This demonstration is approved through December 31, 2020.

The STCs have been arranged into the following subject areas:

I. Preface
II. Program Description and Objectives
III. General Program Requirements
IV. Affected Populations and Populations Made Eligible under the Demonstration
V. Benefits
VI. Cost Sharing
VII. Delivery System
VIII. General Reporting Requirements
IX. General Financial Requirements
X. Monitoring Budget Neutrality for the Demonstration
XI. Evaluation of the Demonstration
XII. Schedule of State Deliverables During the Demonstration

II. PROGRAM DESCRIPTION AND OBJECTIVES

Indiana's HIP 1.0 demonstration began in 1994 to supplement state plan benefits for Medicaid eligible children and otherwise eligible adults who are not aged, blind or disabled.
HIP 1.0 utilized an account similar to a health savings account called a Personal Wellness and Responsibility (POWER) account to cover uninsured parents as well as childless adults whose incomes are below 200 percent of the federal poverty level (FPL). HIP 1.0 was scheduled to expire at the end of 2013, but was extended for an additional year through December 31, 2014.

In May 2014, CMS approved an amendment to include former spend down enrollees diagnosed with End Stage Renal Disease (ESRD) as a HIP 1.0 demonstration population. ESRD enrollees are Medicare beneficiaries in need of supplemental health care coverage. By providing coverage through HIP, beneficiaries were able to access kidney transplant and related services that they might not be able to afford without the additional supplemental benefits.

In January 2015, CMS approved the Healthy Indiana Plan 2.0 (HIP 2.0) demonstration, which provides health care coverage for adults through a managed care plan and a POWER account. The demonstration includes POWER account contributions, implements healthy behavior incentives, and a premium assistance program for individuals with employer sponsored insurance. Former HIP 1.0 enrollees transitioned into the HIP 2.0 demonstration, and the ESRD enrollees were the only population remaining in the HIP 1.0 demonstration. The HIP 1.0 demonstration with only the ESRD enrollees left has been operating on temporary extension since January 2016 (and currently expires July 31, 2016).

Since the ESRD population is the only one that remains in this demonstration, it has been renamed End Stage Renal Disease (ESRD). This demonstration will continue to provide coverage for individuals with ESRD that are not currently eligible under the Medicaid state plan. The demonstration covers approximately 350 individuals with ESRD, who would otherwise be unable to access kidney transplant services.

With this demonstration extension, Indiana expects to achieve the following Medicaid program objectives:

- Increase overall coverage of low-income individuals with a diagnosis of ESRD in the state; and
- Ensure access to comprehensive coverage for low-income individuals who have a diagnosis of ESRD and primary coverage through Medicare.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

2. **Compliance with Medicaid Law, Regulation, and Policy.** All requirements of the Medicaid program expressed in law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents, of which these terms and conditions are part, must apply to the demonstration, including the protections for Indians pursuant to section 5006 of the American Recovery and Reinvestment Act of 2009.

3. **Changes in Medicaid Law, Regulation, and Policy.** The state must, within the time frames specified in law, regulation, or policy statement, come into compliance with

any changes in federal law, regulation, or policy affecting the Medicaid program that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes of an operation nature without requiring the state to submit an amendment to the demonstration under STCs 6 and 7. CMS will notify the state within 30 days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.

4. **Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**

    a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement for the demonstration, as necessary, to comply with such change. The modified budget neutrality agreement would be effective upon implementation of the change.

    b. If mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law.

5. **State Plan Amendments.** The state shall not be required to submit title XIX state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population covered through the Medicaid state plan is affected by a change to the demonstration, a conforming amendment to the state plan may be required, except as otherwise noted in these STCs.

6. **Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, enrollee rights, delivery systems, cost sharing, evaluation design, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS. Amendments to the demonstration are not retroactive and FFP will not be available for changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below.

7. **Demonstration Amendment Process.** Requests to amend the demonstration must be submitted to CMS for approval no later than 120 days prior to the date of implementation of the change and may not be implemented until approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required reports and other deliverables in a timely fashion according to the

deadlines specified herein. Amendment requests must include, but are not limited to, the following:

a. An explanation of the public process used by the state, consistent with the requirements of STC 14, to reach a decision regarding the requested amendment.

b. A data analysis which identifies the specific "with waiver" impact of the proposed amendment on the current budget neutrality agreement. Such analysis shall include current total computable "with waiver" and "without waiver" status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the "with waiver" expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;

c. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation, including a conforming title XIX state plan amendment, if necessary; and,

d. If applicable, a description of how the evaluation design will be modified to incorporate the amendment provisions.

8. Extension of the Demonstration. States that intend to request demonstration extensions under sections 1115(a), 1115(e) or 1115(f) are advised to observe the timelines contained in those statutes. Otherwise, no later than 6 months prior to the expiration date of the demonstration, the governor or chief executive officer of the state must submit to CMS either a demonstration extension request or a phase-out plan consistent with the requirements of STC 9. As part of the demonstration extension requests, the state must provide the documentation of compliance with the transparency requirements 42 CFR Section 431.412 and the public notice and tribal consultation requirements outlined in STC 14.

9. Demonstration Phase-Out. The state may suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

a. Notification of Suspension or Termination: The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a phase-out plan. The state must submit its notification letter and a draft phase-out plan to CMS no less than 6 months before the effective date of the demonstration's suspension or termination. Prior to submitting the draft phase-out plan to CMS, the state must publish on its website the draft phase-out plan for a 30-day public comment period. In addition, the state must conduct tribal consultation in accordance with its approved tribal consultation state plan amendment. Once the 30-day public comment period has ended, the state must provide a summary of each public comment received the state's response to the comment and how the state incorporated the received comment into a revised phase-out plan.

The state must obtain CMS' approval of the phase-out plan prior to the implementation of the phase-out activities. Implementation of phase-out activities must be no sooner than 14 days after CMS approval of the phase-out plan.

b. Phase-out Plan Requirements: The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid eligibility for the affected beneficiaries, and ensure ongoing coverage for eligible individuals, as well as any community outreach activities.

c. Phase-out Procedures: The state must comply with all notice requirements found in 42 CFR sections 431.206, 431.210, and 431.213. In addition, the state must assure all appeal and hearing rights afforded to demonstration participants as outlined in 42 CFR sections 431.220 and 431.221. If a demonstration participant requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR section 431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid eligibility under a different eligibility category as discussed in the October 1, 2010 CMS State Health Official Letter #10-008.

d. Federal Financial Participation (FFP): If the project is terminated or any relevant waivers suspended by the state, FFP shall be limited to normal closeout costs associated with terminating the demonstration including services and administrative costs of disenrolling participants.

10. **CMS Right to Terminate or Suspend.** CMS may suspend or terminate the demonstration (in whole or in part) at any time before the date of expiration whenever it determines following a hearing, that the state has materially failed to comply with the terms of the project. CMS shall promptly notify the state in writing of the determination and the reasons for the suspension or termination, together with the effective date.

11. **Finding of Non-Compliance.** The state does not relinquish its rights to challenge CMS' finding that the state materially failed to comply.

12. **Withdrawal of Waiver Authority.** CMS reserves the right to withdraw waivers or expenditure authorities at any time it determines that continuing the waivers or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX. CMS shall promptly notify the state in writing of the determination and the reasons for the withdrawal, together with the effective date, and shall afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the

waiver or expenditure authorities, including services and administrative costs of disenrolling participants.

13. **Adequacy of Infrastructure.** The state must ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

14. **Public Notice, Tribal Consultation, and Consultation with Interested Parties.** The state must comply with the state Notice Procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994). The state must also comply with the tribal consultation requirements in section 1902(a)(73) of the Act as amended by section 5006(e) of the American Recovery and Reinvestment Act (ARRA) of 2009 and the tribal consultation requirements contained in the state's approved state plan, when any program changes to the demonstration, including (but not limited to) those referenced in STC 6, are proposed by the state.

    In states with federally recognized Indian tribes, consultation must be conducted in accordance with the consultation process outlined in the July 17, 2001, letter or the consultation process in the state's approved Medicaid state plan if that process is specifically applicable to consulting with tribal governments on waivers (42 C.F.R. section 431.408(b)(2)).

    In states with federally recognized Indian tribes, Indian health programs, and/or Urban Indian organizations, the state is required to submit evidence to CMS regarding the solicitation of advice from these entities prior to submission of any demonstration proposal, and/or renewal of this demonstration (42 C.F.R. section 431.408(b)(3)). The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment.

15. **Federal Financial Participation (FFP).** No federal matching funds for expenditures for this demonstration will take effect until the effective date identified in the demonstration approval letter.

IV. AFFECTED POPULATIONS AND POPULATIONS MADE ELIGIBLE UNDER THE DEMONSTRATION

16. **Populations.** This demonstration includes two populations who are made eligible under the demonstration; no state plan populations are affected by the demonstration. Table 1 contains an overview of eligibility under the demonstration.

Table 1: ESRD Demonstration Populations

Description	FPL Level and/or other qualifying criteria	Demonstration Population
Former spend down enrollees effective May 31, 2014	Enrolled in Medicaid spend down effective May 31, 2014, have Medicare, have resources less than $1,500 for an individual and $2,250 for a couple, have income over 150% of FPL, have a diagnosis of ESRD, are not institutionalized, and meet all other Medicaid non-financial eligibility criteria, but not otherwise Medicaid eligible.	Population 1
New Enrollees	Income between 150 and 300% FPL, have Medicare, have a diagnosis of ESRD, have resources less than $1,500 for an individuals and $2,250 for a couple, are not institutionalized, and meet all other Medicaid non-financial eligibility criteria but not otherwise eligible for Medicaid or Demonstration Population 1.	Population 2

17. **Enrollment.** Former spend down enrollees will maintain seamless Medicaid coverage with no administrative action required as long as they continue to meet the applicable eligibility criteria for the demonstration (or for Medicaid coverage on another basis). New enrollees are required to submit an application and complete an in-person assessment.

18. **Redetermination of Eligibility**. Enrollees are required to complete annual eligibility redeterminations. Former spend down enrollees will maintain their ESRD eligibility during their annual redetermination if they meet the following criteria:

    a. Meet the eligibility criteria in effect May 31, 2014 for the aged, blind and disabled groups, including use of a spend down;
    b. Continue to have a physician-verified ESRD diagnosis
    c. Are not institutionalized;
    d. Do not qualify for Medicaid on another basis.

    Individuals are also eligible if they meet the following criteria:

    a. Have been diagnosed with ESRD;
    b. Have a household income below 300 percent of the federal poverty line (FPL);
    c. Have resources below $1,500 for an individual or $2,250 for a couple
    d. Are not institutionalized;
    e. Meet all other Medicaid non-financial eligibility criteria; and
    f. Are not Medicaid eligible on another basis, or eligible in the prior group.

V. BENEFITS

19. ESRD Covered Benefits. Individuals eligible for the demonstration will be eligible for state plan benefits after they meet their ESRD liability. The liability will be calculated using spend down methodology based on incurred medical costs. This coverage is considered Minimal Essential Coverage (MEC).

Services Not Covered
Swing bed in a skilled nursing facility
Long-term care services (nursing facility, home and community based waiver, and ICF/IID services)

Admission to Nursing Facilities: Expenditures incurred for any services received while an ESRD enrollee is an inpatient in a long term care institutional setting will not be claimed under the demonstration. Any individual enrolled in the ESRD demonstration who is admitted to a nursing facility or other long term care setting, either temporarily (for less than 30 days) or for a longer admission, will be assessed for eligibility under a Medicaid State Plan covered category. Such individuals will be disenrolled from the demonstration upon admission to an institution and assessed for re-enrollment into the demonstration upon discharge from the institutional setting.

20. Non-Emergency Medical Transportation (NEMT). Individuals affected by this demonstration shall receive benefits in the form of an administrative activity or service to assure non-emergency transportation to and from providers. The state must report in the quarterly reports any complaints or issues regarding NEMT.

VI. COST SHARING

21. Allowable Cost Sharing. Enrollees will be subject to the same cost sharing as described in the approved Medicaid state plan.

VII. DELIVERY SYSTEM

22. Fee for Service. The participants in the demonstration will receive services through a fee-for-service delivery system.

VIII. GENERAL REPORTING REQUIREMENTS

23. General Financial Requirements. The state shall comply with all general financial requirements under title XIX set forth in these STCs.

24. Reporting Requirements Relating to Budget Neutrality. The state shall comply with all reporting requirements for monitoring budget neutrality set forth in this agreement. The state must submit any corrected budget neutrality data upon request.

25. Monitoring Calls. CMS will have monitoring calls with the state. The purpose of these calls is to discuss any significant actual or anticipated developments affecting the demonstration.

26. Quarterly Progress Reports: The state must submit progress reports in accordance with the guidelines in Attachment A by no later than 60 days following the end of each quarter (March, June, September, and December of each year). The intent of these reports is to present the state's analysis and the status of the various operational program areas. These quarterly reports must include, but not be limited to:

a. An updated budget neutrality monitoring spreadsheet;

b. A discussion of events occurring during the quarter or anticipated to occur in the near future that affect health care delivery, including, but not limited to: approval and contracting with new plans, benefits, enrollment and disenrollment, grievances, quality of care, access, health plan contract compliance and financial performance that is relevant to the demonstration, pertinent legislative or litigation activity, and other operational issues;

c. Action plans for addressing any policy, administrative, or budget issues identified;

d. Quarterly enrollment reports for demonstration eligibles that include the member months for each demonstration population, as required to evaluate compliance with the budget neutrality agreement, and as specified in Section IX, STC 29; and other statistical reports listed in Attachment A.

27. Annual Report.

a. The state shall submit a draft annual report documenting accomplishments, project status, quantitative and case study findings, utilization data, interim evaluation findings, and policy and administrative difficulties and solutions in the operation of the demonstration.

b. The state shall submit the draft annual report by no later than 120 days after the end of each demonstration year (DY) for CMS review. The state shall finalize and submit the final draft report within 60 days from receipt of CMS' comments.

IX. GENERAL FINANCIAL REQUIRMENTS

28. Quarterly Expenditure Reports. The state must provide quarterly expenditure reports using the form CMS-64 to report total expenditures for services provided under the Medicaid program, and to separately identify expenditures provided through the demonstration under section 1115 authority, which are subject to budget

neutrality. This project is approved for expenditures applicable to services rendered during the demonstration period. CMS shall provide FFP for allowable demonstration expenditures only as long as they do not exceed the pre-defined limits on the costs incurred as specified in Section IX of the STCs.

29. Reporting Expenditures under the Demonstration. The following describes the reporting of expenditures subject to the budget neutrality expenditure limit:

a. **Tracking Expenditures.** In order to track expenditures under this demonstration, Indiana must report demonstration expenditures through the Medicaid and Children's Health Insurance Program Budget and Expenditure System (MBES/CBES), following routine CMS-64 reporting instructions outlined in section 2500 of the State Medicaid Manual. All demonstration expenditures claimed under the authority of title XIX of the Act and subject to the budget neutrality expenditure limit must be reported each quarter on separate Forms CMS-64.9 Waiver and/or 64.9P Waiver, identified by the demonstration project number assigned by CMS, including the project number extension, which indicates the DY in which services were rendered or for which capitation payments were made. For this purpose, DY 9 is defined as the year beginning January 1, 2016. Subsequent DYs are defined accordingly. All title XIX service expenditures that are not demonstration expenditures and are not part of any other title XIX waiver program should be reported on Forms CMS-64.9 Base/64.9P Base.

b. **Cost Settlements.** For monitoring purposes, cost settlements attributable to the demonstration must be recorded on the appropriate prior period adjustment schedules (Form CMS-64.9P Waiver) for the Summary Sheet Line 10B, in lieu of Lines 9 or 10C. For any cost settlements not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual.

c. **Use of Waiver Forms**. The following waiver Form CMS-64.9 Waiver and/or 64.9P Waiver must be submitted each quarter (when applicable) to report title XIX expenditures for individuals enrolled in the demonstration. The expressions in quotation marks are the waiver names to be used to designate these waiver forms in the MBES/CBES system.

    i. **Demonstration Population 1: Former Spend Down Individuals** that were enrolled in Medicaid spend down effective May 31, 2014, have Medicare, meet resource requirements limit of $1,500 for an individual and $2,250 for a couple, over 150 percent of the FPL, have a diagnoses of ESRD, not institutionalized, and meet applicable non-financial Medicaid eligibility requirements; and

    ii. **Demonstration Populations 2: New Enrollees** with incomes between 150 and 300 percent of the FPL, have Medicare, are diagnosed with

ESRD, have resources less than $1,500 for an individuals and $2,250 for a couple, at not institutionalized, and meet applicable non-financial Medicaid eligibility criteria requirements, but are not eligible for Medicaid or Demonstration Population 1.

d. **Pharmacy Rebates.** The state may propose a methodology for assigning a portion of pharmacy rebates to the demonstration, in a way that reasonably reflects the actual rebate-eligible pharmacy utilization of the demonstration population, and which reasonably identifies pharmacy rebate amounts with DYs. Use of the methodology is subject to the approval in advance by the CMS Regional Office, and changes to the methodology must also be approved in advance by the Regional Office. The portion of pharmacy rebates assigned to the demonstration using the approved methodology will be reported on the appropriate Forms CMS-64.9 Waiver for the demonstration, and not on any other CMS-64.9 form (to avoid double-counting). Each rebate amount must be distributed as state and federal revenue consistent with the federal matching rates under which the claim was paid.

e. **Title XIX Expenditures Subject to the Budget Neutrality Expenditure Limit**. For the purpose of this section, the term "expenditures subject to the budget neutrality expenditure limit" refers to all title XIX expenditures on behalf of individuals who are enrolled in this demonstration, as defined in Section IV, STC 16, including all service expenditures net of premium collections and other offsetting collections. All title XIX expenditures that are subject to the budget neutrality expenditure limit are considered demonstration expenditures and must be reported on Forms CMS-64.9 Waiver and/or CMS-64.9P Waiver.

f. **Administrative Costs.** The following provisions govern reporting of administrative costs during the demonstration.

   i. Administrative costs attributable to the demonstration must be reported under the waiver name "ESRD." These expenses are not subject to the budget neutrality limit.

   ii. Administrative costs not related to the demonstration should be reported on the appropriate CMS-64.10 Base or 64.10P Base, or another waiver schedule as appropriate, and not subject to the budget neutrality test for this demonstration.

g. **Claiming Period**. All claims for expenditures subject to the budget neutrality expenditure limit (including any cost settlements) must be made within 2 years after the calendar quarter in which the state made the expenditures. Furthermore, all claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter 2-year period, the state must continue to identify separately on the CMS-64 waiver forms the net expenditures related to

dates of service during the operation of this demonstration, in order to account for these expenditures properly to determine budget neutrality.

30. Reporting Member Months: The following describes the reporting of member months for HIP:

a. For the purpose of calculating the budget neutrality expenditure limit, the state must provide to CMS, as part of the quarterly report required under Section VIII, STC 25, the actual number of eligible member months for all HIP eligibility groups defined in Section IV, STC 16.

b. Member months are defined as the number of months in which persons are eligible to receive services. For example, a person who is eligible for 3 months contributes three eligible member months to the total. Two individuals who are eligible for 2 months each contribute two eligible member months to the total, for a total of 4 eligible member months.

31. Standard Medicaid Funding Process. The standard Medicaid funding process must be used during the demonstration. The state must estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the Form CMS-37 (narrative section) for both the Medical Assistance Payments (MAP) and state and Local Administration Costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within 30 days after the end of each quarter, the state must submit the Form CMS-64 quarterly Medicaid expenditure report, showing Medicaid expenditures made in the quarter just ended. CMS shall reconcile expenditures reported on the Form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

32. Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS shall provide FFP at the applicable federal matching rates for the demonstration as a whole as outlined below, subject to the budget neutrality limits described in Section IX.

a. Administrative costs, including those associated with the administration of the demonstration;

b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan and waiver authorities;

c. Net expenditures and prior period adjustments, made under approved Expenditure Authorities granted through section 1115(a)(2) of the Act, with dates of service during the operation of the demonstration.

33. Sources of Non-Federal Share. The state provides assurance that the matching non-federal share of funds for the demonstration is state/local monies. The state further assures that such funds shall not be used as the match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

a. CMS may review at any time the sources of the non-federal share of funding for the demonstration. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.

b. Any amendments that impact the financial status of the program shall require the state to provide information to CMS regarding all sources of the non-federal share of funding.

c. Under all circumstances, health care providers must retain 100 percent of the ESRD reimbursement amounts claimed by the state as demonstration expenditures. Moreover, no pre-arranged agreements (contractual or otherwise) may exist between the health care providers and the state and/or local government to return and/or redirect any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business (such as payments related to taxes (including health care provider-related taxes), fees, and business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments) are not considered returning and/or redirecting a Medicaid payment.

34. Monitoring the Demonstration. The state shall provide CMS with information to effectively monitor the demonstration, upon request, in a reasonable timeframe.

X. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

35. Limit on Title XIX Funding. The state shall be subject to a limit on the amount of federal title XIX funding that the state may receive on selected Medicaid expenditures during the period demonstration approval period. The limit will consist of two parts, and is determined by using a per capita cost method, with an aggregate adjustment for projected DSH payments. The budget neutrality expenditure targets are set on a yearly basis with a cumulative budget neutrality expenditure limit for the length of the entire demonstration. Actual expenditures subject to the budget neutrality expenditure limit shall be reported by the state using the procedures described in Section VIII, STC 23.

36. Future Adjustments to the Budget Neutrality Expenditure Limit. CMS reserves the right to adjust the budget neutrality expenditure limit to be consistent with enforcement of impermissible provider payments, health care related taxes, new federal statutes, or policy interpretations implemented through letters, memoranda, or regulations with respect to the provision of services covered under the ESRD demonstration.

37. Calculation and Application of Budget Neutrality Limit

The state is paying for the ESRD expenditure population with accumulated total computable budget neutrality savings. The demonstration is expected to cost $9,445,617 (total computable) over the five years.

The cost of the ESRD expenditure population for each year of the extension period is expected to be:

	DY09 (CY2016)	DY10 (CY2017)	DY11 (CY2018)	DY12 (CY2019)	DY 13 (CY2020)
Eligible Member Months	4,290	4,247	4,205	4,163	4,121
PMPM with Trend Rate of 4%	$424.04	$436.38	$449.18	$462.25	$475.70

38. Enforcement of Budget Neutrality. CMS shall enforce budget neutrality over the life of the demonstration rather than on an annual basis, by combining the annual limits calculated into lifetime limits for the demonstration. The following describes how budget neutrality will be enforced.

a. If the demonstration is terminated prior to the end of the budget neutrality agreement, an assessment of the state's compliance with these requirements shall be based on the time elapsed through the termination date.

b. **Interim Checks/Corrective Action Plan.** If the state exceeds the calculated cumulative target limit combined by the percentage identified below for any of the DYs, the state shall submit a corrective action plan to CMS for approval.

DY	Cumulative Target Definition	Percentage
Year 9	Cumulative budget neutrality expenditure cap plus:	1 percent
Year 10	Cumulative budget neutrality expenditure cap plus:	1 percent
Year 11	Cumulative budget neutrality expenditure cap plus:	0.5 percent
Year 12	Cumulative budget neutrality expenditure cap plus:	0.5 percent
Year 13	Cumulative budget neutrality expenditure cap plus:	0 percent

XI. EVALUATION OF THE DEMONSTRATION

39. Submission of Draft Evaluation Design. The state must submit to CMS for approval an updated draft evaluation design for an overall evaluation of the demonstration by no later than 120 days after the effective date of the demonstration. At a minimum, the draft design must include a discussion of the goals and objectives set forth in Section II of these STCs, as well as the specific hypotheses that are being tested. The draft design

must discuss the outcome measures that will be used in evaluating the impact of the demonstration during the period of approval. It shall discuss the data sources and sampling methodology for assessing these outcomes. The draft evaluation design must include a detailed analysis plan that describes how the effects of the demonstration must be isolated from other initiatives occurring in the state. The draft design must identify whether the state will conduct the evaluation, or select an outside contractor for the evaluation.

40. Interim Evaluation Reports. In the event the state requests to extend the demonstration beyond the current approval period under the authority of section 1115(a), (e), or (f) of the Act, the state must submit an interim evaluation report as part of the state's request for each subsequent renewal.

41. Final Evaluation Design and Implementation. CMS shall provide comments on the draft evaluation design, and the state shall submit a final design within 60 days after receipt of CMS comments. The state must implement the evaluation design and submit its progress in each of the quarterly and annual progress reports. The state must submit to CMS a draft of the evaluation report within 120 days after expiration of the demonstration. CMS will provide comments after receipt of the report. The state must submit the final evaluation report within 60 days after receipt of CMS comments.

42. Cooperation with Federal Evaluators. Should CMS undertake an independent evaluation of any component of the demonstration, the state shall cooperate fully with CMS or the independent evaluator selected by CMS. The state shall submit the required data to CMS or the contractor.

XII. SCHEDULE OF STATE DELIVERABLES DURING THE DEMONSTRATION

Date Specific	Deliverable	STC Reference
120 days after date of approval letter	Submit Draft Evaluation Design	Section XI, STC 39
60 days after receipt of CMS comments	Final Evaluation Design	Section XI, STC 41
Annual	By May 1st - Draft Annual Report	Section VIII, STC 27
Quarterly		
	Deliverable	**STC Reference**
60 days after the end of the quarter	Quarterly Progress Reports	Section VIII, STC 26
	Quarterly Expenditure Reports	Section IX, STC 28
	Eligible Member Months	Section IX, STC 29

Attachment A

Quarterly Program Report Guidelines

Under Section VII, STC 26, the state is required to submit quarterly progress reports to CMS. The purpose of the quarterly report is to inform CMS of significant demonstration activity from the time of approval through completion of the demonstration. The reports are due to CMS 60 days after the end of each quarter.

The following report guidelines are intended as a framework and can be modified when agreed upon by CMS and the state. A complete quarterly progress report must include an updated budget neutrality monitoring workbook. An electronic copy of the report narrative, as well as the Microsoft Excel workbook is provided.

NARRATIVE REPORT FORMAT:

Title Line One – End Stage Renal Disease Demonstration

Title Line Two - Section 1115 Quarterly Report

Demonstration/Quarter Reporting Period:

Example:
Demonstration Year: 1 (1/01/16 - 12/31/16)
Federal Fiscal Quarter: 2/2016 (1/16 - 3/16)

Introduction:

Information describing the goal of the demonstration, what it does, and key dates of approval/ operation. (This should be the same for each report.)

1. Report member-months for budget neutrality:

A. For Use in Budget Neutrality Calculations

Eligibility Group	Month 1	Month 2	Month 3	Total for Quarter Ending XX/XX
Former Spend Down Individuals				
New Enrollees				

Outreach/Innovative Activities:

Summarize outreach activities and/or promising practices for the current quarter.

Operational/Policy Developments/Issues:

Identify all significant program developments/issues/problems that have occurred in the current quarter, including, but not limited to, approval and contracting with new plans, benefit changes, legislative activity, and non-emergency medical transportation.

Financial/Budget Neutrality Developments/Issues:
Identify all significant developments/issues/problems with financial accounting, budget neutrality, and CMS-64 reporting for the current quarter. Identify the state's actions to address these issues.

Consumer Issues:
A summary of the types of complaints or problems consumers identified about the program in the current quarter. Include any trends discovered, the resolution of complaints, and any actions taken or to be taken to prevent other occurrences.

Quality Assurance/Monitoring Activity:
Identify any quality assurance/monitoring activity in current quarter.

Demonstration Evaluation
Discuss progress of evaluation design and planning.

Enclosures/Attachments:
Identify by title any attachments along with a brief description of what information the document contains.

State Contact(s):
Identify individuals by name, title, phone, fax, and address that CMS may contact should any questions arise.

Date Submitted to CMS: