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PHARMACY PLUS

A DEMONSTRATION PROGRAM UNDER SECTION 1115

Model Special Terms and Conditions of Approval

CENTERS FOR MEDICARE & MEDICAID SERVICES
DRAFT SPECIAL TERMS AND CONDITIONS

NUMBER: (11-W100XXX/XX)

TITLE: Pharmacy Plus

AWARDEE: State & Department Name

The following are Special Terms and Conditions for the award of Pharmacy Plus Medicaid demonstration proposal submitted on XXXX requesting authority under Section 1115 of the Social Security Act (the Act). The Special Terms and Conditions are arranged in eight subject areas: General Program Requirement and Agreements, General Reporting Requirements, Legislation, Assurances, Upper Payment Limit Reporting, Operational Protocol, and Attachments regarding General Financial Requirements, Monitoring Budget Neutrality, and a Summary Schedule of Reporting Items.

Letters, documents, reports, or other materials that are submitted for review or approval will be sent to Centers for Medicare & Medicaid Services (CMS) central office demonstration Project Officer and the state representative in the CMS regional office.

Sample– Special Terms and Conditions will be prepared for each demonstration project.

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I. GENERAL PROGRAM REQUIREMENTS AND AGREEMENTS

1. **Extension or phase-out plan.** Demonstration extension plans will be discussed with CMS at least 18 months prior to demonstration expiration, and requests for extensions are due to CMS no later than 12 months prior to the expiration of the demonstration. If the state does not request an extension, it will submit a phase-out plan, which includes provisions for cessation of enrollment, to CMS no later than 12 months prior to the expiration of the demonstration. The phase-out plan is subject to CMS review and approval.

2. **Enrollment limitation during last 6 months.** New enrollment is not permitted during the last 6 months of the demonstration unless the demonstration authority is extended by CMS.

3. **Cooperation with Federal evaluators.** The state will design and conduct an evaluation of the demonstration program. The state will fully cooperate with Federal evaluators and their contractor's efforts to conduct an independent federally funded evaluation of the demonstration program.

4. **CMS right to suspend or preclude demonstration implementation.** The CMS may suspend or preclude Federal Financial Participation (FFP) for state demonstration implementation and/or service provision to demonstration enrollees whenever CMS determines that the state has materially failed to comply with the terms of the project, and/or that the implementation of the project does not further the goals of the Medicaid program.

5. **State right to terminate or suspend demonstration.** The state may suspend or terminate this demonstration in whole or in part at any time before the date of expiration. If the state chooses to terminate this demonstration before the expiration date, it will notify CMS in writing at least 30 days prior to terminating services to participants. If CMS or the state terminate the demonstration, the state will, at least 30 days prior to terminating services, notify participants of services of the action it intends to take, notify them of the effective date of the action, and how the action will affect the participants.

6. **CMS right to terminate or suspend demonstration operation.** During demonstration operation, CMS may suspend or terminate FFP for any project in whole or in part at any time before the date of expiration, whenever it determines that the state has materially failed to comply with the terms of the project. The CMS will promptly notify the state in writing of the determination and the reasons for the suspension or termination. The effective date of such action shall not be fewer than 45 days from the date of notice. The state waives none of its rights under 42 CFR 430, Grants to States for Medical Assistance Programs, to challenge CMS's finding that the state materially failed to comply. The CMS reserves the right to withhold waivers and authority for pending FFP for costs not otherwise matchable or to withdraw waivers or authority for costs not otherwise matchable at any time if it determines that granting or continuing the waivers or authority for costs not otherwise matchable would no longer be in the public interest. If the waiver or authority for costs not otherwise matchable is withdrawn, CMS will be liable only for normal close-out costs.

II. GENERAL REPORTING REQUIREMENTS

(Attachment C provides a summary of the frequency of required reporting items)

7. **Monthly progress calls.** Before implementation and for six months after implementation CMS and the state will hold monthly calls to discuss demonstration progress. After six months of operation, CMS and the state will determine the appropriate frequency of progress calls.

8. **Quarterly & annual progress reports.** The state will submit quarterly progress reports that are due 60 days after the end of each quarter. The fourth quarterly report of every calendar year will include an overview of the past year as well as the last quarter, and will serve as the annual progress report. The CMS reserves the right to request the annual report in draft. The reports will address, at a minimum:
   - a discussion of events occurring during the quarter (including enrollment numbers, lessons learned, and a summary of expenditures);
   - notable accomplishments; and
   - problems/issues that were identified and how they were solved.

9. Final report. At the end of the demonstration period, a draft final report will be submitted to CMS for comments. The CMS's comments shall be taken into consideration by the state for incorporation into the final report. The CMS's document *Author's Guidelines: Grants and Contracts Final Reports* is available to the state upon request. The final report with CMS' comments is due no later than 180 days after the termination of the project. The state will include a discussion of its evaluation results in the final report.

III. LEGISLATION

10. Changes in the enforcement of laws, regulations, and policy statements. All requirements of the Medicaid program expressed in Federal laws, regulations, and policy statements, not expressly waived or identified as not applicable in the award letter of which these Special Terms and Conditions are part, will apply to the demonstration. To the extent that changes in the enforcement of such laws, regulations, and policy statements would have affected state spending in the absence of the demonstration in ways not explicitly anticipated in this agreement, CMS will incorporate such effects into a modified budget limit for the demonstration. The modified budget limit would be effective upon enforcement of the law, regulation, or policy statement.

If the law, regulation, or policy statement imposes a financial responsibility or limitation but cannot be identified specifically with demonstration or non-demonstration components of the overall state program (e.g., all disallowances involving provider taxes or donations), the effect of enforcement on the state's budget limit will be proportional to the size of the demonstration in comparison to the state's entire Medicaid program (as measured in aggregate medical assistance payments).

11. Changes in Federal law affecting Medicaid. The state will, within the time frame specified in law, come into compliance with any changes in Federal law affecting the Medicaid program that occur after the demonstration award date. To the extent that a change in Federal law, which does not exempt state section 1115 Medicaid demonstrations, would affect state Medicaid spending in the absence of the demonstration, CMS will incorporate such changes into a modified budget limit for the demonstration. The modified budget limit will be effective upon implementation of the change in Federal law, as specified in law.

If the new law cannot be linked specifically with program components that are or are not affected by the demonstration (e.g., laws affecting sources of Medicaid funding), the state will submit its methodology to CMS for complying with the change in law. If the methodology is consistent with Federal law and in accordance with Federal projections of the budgetary effects of the new law in the state, CMS would approve the methodology. Should CMS and the state, working in good faith to ensure state flexibility, fail to develop within 90 days a methodology to revise the without waiver baseline that is consistent with Federal law and in accordance with Federal budgetary projections, a reduction in Federal payments will be made according to the method applied in non-demonstration states.

12. Amending the demonstration. The state may submit an amendment for CMS consideration requesting exemption from changes in law occurring after the demonstration award date. The cost to the Federal Government of such an amendment must be offset to ensure that total projected expenditures under a modified demonstration program do not exceed projected expenditures in the absence of the demonstration (assuming full compliance with the change in law).

Sample– Special Terms and Conditions will be prepared for each demonstration project.

IV. ASSURANCES

Acceptance of the Special Terms and Conditions of Approval constitutes the state's assurance of the following:

13. **Assurances included in application.** All Assurances checked in the Pharmacy Plus Application (Section II) by this reference become included as items in these Special Terms and Conditions of Approval, and will be fulfilled as part of the Special Terms and Conditions of Approval.

14. **Preparation, approval, and changes to operational protocol.** Prior to service delivery under this demonstration, an operational protocol document, which represents all policies and operating procedures applicable to this demonstration, will be prepared by the state and approved by CMS. The state acknowledges that CMS reserves the right not to approve an operational protocol in the event that it does not comply with the Special Terms and Conditions of Approval. *Requirements and required contents of the operational protocol are outlined in Section V of these Special Terms and Conditions.*

15. **Screening for Medicaid eligibility.** Individuals applying for this demonstration will be screened to determine eligibility under the approved state Medicaid plan. Individuals found through screening to be potentially eligible under the approved state plan will be informed of the option to apply for benefits (including a prescription drug benefit) under the state plan and will be provided information about the state plan benefit as well as information about how to apply for the state plan benefit. Such individuals who elect not to apply under the state plan, and meet the criteria for enrollment in the demonstration, may be enrolled in the demonstration.

16. **Adequacy of infrastructure.** Adequate resources for implementation, monitoring activities, and compliance to the Special Terms and Conditions of the Pharmacy Plus demonstration will be provided by the state.

17. **Reporting of drug utilization and collection of rebates.** Drug utilization will be reported pursuant to section 1927(b)(2)(A) of the Act, and rebates will be collected for only those covered outpatient drugs for which the state has made a payment.

18. **Pharmacy services management.** The demonstration includes appropriate methodologies, oversight and review of pharmacy services that promote efficient and medically appropriate use of services by enrollees.

V. UPPER PAYMENT LIMIT REPORTING

18. The state will provide information on a quarterly basis regarding the amount of payments made to providers both inside and outside of the demonstration budget neutrality cap, subject to 42 CFR 447.272 and 42 CFR 447.321. The sum of payments both included and excluded from the demonstration budget neutrality cap for services governed by 42 CFR 447.272 and 42 CFR 447.321 must not exceed their respective upper payment limits. The state also may not claim budget neutrality savings attributed to reductions in payments originally assumed in the budget neutrality ceiling calculations if a corresponding increase in enhanced payments for these services is made outside the scope of the budget neutrality agreement.

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VI. OPERATIONAL PROTOCOL

19. Operational protocol timelines and requirements. The operational protocol will be submitted to CMS no later than 60 days prior to program implementation (or another date agreed upon by CMS and the state). The CMS will respond within 30 days of receipt of the protocol (or another date agreed upon by CMS and the state) regarding any issues or areas for which clarification is needed in order to fulfill the Special Terms and Conditions, those issues being necessary to approve the operational protocol.

Subsequent changes to the demonstration program and the operational protocol that are the result of major changes in policy or operating procedures, including changes to cost-sharing amounts, subsidy amounts, or adjustments for inflation, will be submitted for review by CMS. The state will submit a request to CMS for these changes no later than 90 days prior to the date of implementation of the change(s).

FFP is not available for Medical assistance payments prior to CMS approval of the operational protocol. The FFP is available for post-approval project development and implementation, and compliance with Special Terms and Conditions.

20. Required contents of operational protocol:

a. Organization and structural administration. A description of the organizational and structural administration that will be in place to implement, monitor, and operate the demonstration, and the tasks each organizational component will perform. Include details such as:

- a timeline of demonstration implementation tasks prior to and post implementation, including steps, estimated time of completion, and who will be responsible for items (for example: necessary pre-implementation data systems changes, when edits will be made, when changes will be tested, and the responsible party);
- claims processing;
- pharmacy benefit manager contract operations and oversight;
- dispensing; and,
- enrollee cost-sharing collections.

b. Reporting items. A description of the content and frequency of each of the reporting items as listed in the Special Terms and Conditions Section II and Attachments A and C of this document.

c. Premiums and cost sharing. A description of the calculation and collection of applicable enrollee cost sharing. Include the following:

- premiums and cost sharing amounts and how they were calculated;
- how they will be reported to CMS (refer to items 2.d. and 6. of Attachment A of this document; and,
- the process through which enrollees and providers will be informed of enrollee financial obligations.

d. Premium and cost sharing protections. A description of the enrollee protections in place regarding state disenrollment of enrollees due to non-compliance with premium and cost sharing requirements for demonstration participation, and how enrollees will be informed. For example:

- the grace period during which enrollees may make the payment without termination from the program;
- how the state will notify the enrollee that he or she has failed to make the required payment and may face termination from the program if the payment is not made;
- how the individual will be assured the right to appeal any adverse actions for failure to pay fees; and,
- the process in place to re-enroll the individual in the demonstration if payment of the required fee is made.

e. Coordination with private health insurance coverage. A description of applicable wraparound benefits and subsidies related to coordination with other private health insurance coverage. Include information about subsidies/cost sharing assistance for Medicare products and/or private health insurance coverage, such as:

- amounts;
- how they were calculated;
- how enrollees and other stakeholders will be informed and assisted through the process of obtaining these payments; and,
- state efforts to avoid crowd-out of existing private health insurance pharmacy coverage.

f. Pharmacy services, providers, and benefit management. A description of the following:

- pharmaceutical services that are included in the demonstration;
- method of services provision (for example, Fee-for-Service or managed care);
- detailed description of the role of a pharmacy benefit manager;
- which practitioners will be providing care;
- how the state will ensure access to an adequate number of pharmacies;
- the methodology for determining reimbursement to providers;
- the interaction of a state only funded pharmacy program and the demonstration; and,
- how any accompanying pharmacy service, such as a prior authorization system, will be utilized under the demonstration.

g. Related medical management. A description of the mechanism in place to ensure that demonstration participants utilizing services have coverage of basic primary care health services that will assist with medical management related to pharmacy products prescribed.

h. Outreach/marketing/education. A description of the state's outreach, marketing, education, and staff training strategy. NOTE: *All marketing materials will be reviewed and approved by CMS prior to use.* Include in the description:

- information that will be communicated to enrollees, participating providers, and State outreach/education/intake staff (such as social services workers and caseworkers);
- types of media to be used;

- specific geographical areas to be targeted;
- locations where such information will be disseminated;
- staff training schedules, schedules for state forums or seminars to educate the public; and,
- the availability of bilingual materials/interpretation services and services for individuals with special needs. Include a description of how eligibles will be informed of cost sharing responsibilities.

i. Eligibility/enrollment. A description of the population of individuals eligible for the demonstration (and eligibility exclusions), including plans for population phase-in. Describe the processes for:

- eligibility determination;
- annual redetermination;
- intake, enrollment, and disenrollment;
- establishment, if applicable, of an enrollment ceiling, including details regarding enforcement of the enrollment ceiling;
- operation, if applicable, of a waiting list, including how individuals are selected from the waiting list to enter the demonstration, how the list is maintained, how individuals on the list are informed of status, and how the intake workers will be able to access the waiting list;
- if applicable, procedures for determining the existence and scope of a demonstration applicant's existing third party liability; and,
- how these demonstration processes will be coordinated with Medicaid program eligibility and enrollment processes.

j. Quality. An overall quality assurance monitoring plan that includes:

- a discussion of how the state will monitor operations of the program (personnel and systems);
- the system in place to trigger and alert state staff to issues that need attention;
- all quality indicators to be employed to monitor products delivered under the demonstration and methodology for measuring such indicators;
- the system in place to ensure that feedback from quality monitoring will be incorporated into the program;
- quality monitoring surveys to be conducted, and the monitoring and corrective action plans to be triggered by the surveys;
- fraud control provisions and monitoring; and,
- information that will be collected to coordinate and monitor pharmacy services as they relate to overall health measures (for example, blood pressure checks every 6 months).

k. Grievances and appeals. If the grievances and appeals policies differ from non-demonstration Medicaid, then provide a description of the grievance and appeal policies that will be in place in the demonstration and how the process will be monitored.

l. Evaluation design. A description of the state's evaluation design, including:

- a discussion of the demonstration hypotheses that will be tested;
- outcome measures that will be included to evaluate the impact of the demonstration;

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- what data will be utilized;
- the methods of data collection;
- how the effects of the demonstration will be isolated from those other initiatives occurring in the state; and,
- any other information pertinent to the state's evaluative or formative research via the demonstration operations.

m. Interaction with other Federal and/or state programs. Describe in detail how pharmacy coverage under the demonstration will interact with other Federal health care benefit programs/grant programs and other state health care benefit programs (for example, Medicaid, Ryan White, and state-only funded pharmacy programs).

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ATTACHMENT A
GENERAL FINANCIAL REQUIREMENTS

1. The state will provide quarterly expenditure reports using the Form CMS-64 to report total expenditures for services provided under the Medicaid program, including those provided through the demonstration under section 1115 Medicaid authority. This project is approved for expenditures applicable to services rendered during the demonstration period. The CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in Attachment B (Monitoring Budget Neutrality for the demonstration).

2. a. In order to track expenditures under this demonstration, the state will report demonstration expenditures through the Medicaid and State 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. Applicable ***rebates and*** expenditures subject to the budget neutrality cap will be reported 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 demonstration year in which services were rendered or for which capitation payments were made). For monitoring purposes, cost settlements will be recorded on Line 10.b, in lieu of Lines 9 or 10c. For any other cost settlements (i.e., those not attributable to this demonstration), the adjustments should be reported on lines 9 or 10.c, as instructed in the State Medicaid manual. The term, "expenditures subject to the budget neutrality cap," is defined below in item 2.c.

b. For each demonstration year a Form CMS-64.9 WAIVER and/or 64.9P WAIVER will be submitted reporting expenditures subject to the budget neutrality cap. The expenditures for individuals enrolled in the demonstration and the non-demonstration ____ group will need to be separately reported through the CMS-64WAIVER reporting system for budget neutrality purposes (including expenditures for this group under all other waiver authorities (i.e., 1915(b), 1915(c), 1115, etc.)). The sum of the expenditures for these two groups, for all demonstration years reported through the quarterly CMS-64 reporting process, will represent the expenditures subject to the budget neutrality cap (as defined in 2. c.). The procedures for the reporting of these expenditures will be described in the operational protocol.

c. For the purpose of this section, the term "expenditures subject to the budget neutrality cap" will include all Medicaid expenditures on behalf of individuals who are enrolled in the demonstration and all expenditures made for service costs for the non-demonstration _____Medicaid eligibility group.

d. Enrollment fees and other applicable cost sharing contributions from enrollees that are collected by the state from enrollees under the demonstration will be reported to CMS on the CMS-64 Summary Sheet on Line 9.D. This will allow CMS to share in the collection of such fees. The state will also separately identify these fees on the narrative form of the CMS-64.

The state will work with CMS to coordinate which enrollee cost sharing information will be reported.

e. Administrative costs will not be included in the budget neutrality limit, but the state must separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs will be reported on the Forms CMS-64.10 WAIVER and/or 64.10P WAIVER.

f. All claims for expenditures subject to the budget neutrality cap (including any cost settlements) will 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) will be made within 2 years after the conclusion or termination of the demonstration. During the latter 2 year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the 1115 Medicaid demonstration on the Form CMS-64 in order to properly account for these expenditures in determining budget neutrality.

g. The procedures related to this reporting process, report contents, and frequency will be discussed by the state in the operational protocol.

3. The standard Medicaid funding and reporting processes will be used during the demonstration. The state must continue to estimate total matchable expenditures for the entire program (including the state plan and the Pharmacy Plus) on the quarterly Form CMS-37. In addition, the estimate of matchable demonstration expenditures (total computable/Federal share) subject to the budget neutrality cap must be separately reported by quarter for each Federal fiscal year on the Form CMS-37.12 for both MAP and ADM. The state must provide supplemental schedules that clearly distinguish between estimates of expenditures subject to the budget neutrality cap (by major component) and estimates of expenditures that are not subject to the cap. CMS will make Federal funds available each quarter based upon the state's estimates, 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 will reconcile expenditures reported on the Form CMS-64 with Federal funding previously made available to the state for that quarter, and include the reconciling adjustment in a separate grant award to the state.

4. The CMS will provide FFP at the applicable Federal matching rate for the following, subject to the limits described in Attachment B:

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 state plan.

c. Net medical assistance expenditures made under Section 1115 demonstration authority,

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including those made in conjunction with the demonstration.

5. The state will certify state/local monies used as matching funds for this Pharmacy Plus Demonstration and will further certify that such funds will not be used as matching funds for any other Federal grant or contract, except as permitted by Federal law.

6. Any enrollee cost sharing collections will be used appropriately to reduce program expenditures prior to determining the level of FFP.

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ATTACHMENT B
MONITORING BUDGET NEUTRALITY

The following describes the method by which budget neutrality will be assured under the demonstration. The Special Terms and Conditions specify the aggregate financial cap on the amount of Federal Title XIX funding that the state may receive on expenditures subject to the budget neutrality cap as defined in 2.c. of Attachment A of this document. The cap places the state at risk for trends in service costs and enrollment. The budget neutrality cap for the 5-year demonstration will be the Federal share of the total computable cost of $ _____. In the event that the state does not begin service delivery to enrollees in the quarter beginning _____, the total computable service costs will be amended for the demonstration period utilizing the same base year (___ Fiscal Year ____) and the same cost trend and enrollment trend increases for the 5-year demonstration period.

The budget neutrality cap for the Pharmacy Plus demonstration is based on the projected cost of services for the impacted population. In this case, the budget neutrality cap includes costs for the state's Medicaid ____ population. The state's demonstration costs and Medicaid ____ population costs will be tracked against the aforementioned budget ceiling amount.

There are two steps involved in the calculation of the projected cost of services budget limit: determining baseline estimates of the number of Medicaid eligibles and the cost per eligible; and determining the method for trending these estimates over time.

The CMS reserves the right to adjust the budget neutrality ceiling to be consistent with enforcement of impermissible provider payments; health care related taxes; new Federal statutes; or policy interpretations implemented through letters, memorandums or regulation; and for technical corrections of data used in the budget neutrality calculations. The CMS reserves the right to make adjustments to the budget neutrality cap if any health care related tax that was in effect during the base year, or provider related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of 1903(w) of the Social Security Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

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The CMS will enforce budget neutrality over the life of the demonstration, rather than on an annual basis. Using the schedule below as a guide, if the state exceeds the cumulative target, it will submit a corrective action plan to CMS for approval. The state will subsequently implement the approved program.

Year	Cumulative target definition	Allowed Margin
Year 1	$X million	8 percent
Year 2	$X million	3 percent
Year 3	$X million	1 percent
Year 4	$X million	0.5 percent
Year 5	$X million	0 percent

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ATTACHMENT C

SUMMARY SCHEDULE OF REPORTING ITEMS

Item	Timeframe for Item	Frequency of Item
Monthly Conference Calls	Prior to demonstration implementation and Post-implementation.	Monthly progress calls with CMS and the state.
Operational Protocol	Due to CMS 90 days prior to implementation, CMS comments 60 days prior to implementation, and state completion/CMS approval prior to implementation.	One operational protocol. Changes to the operational protocol will be submitted and approved by CMS.
Quarterly/Annual Progress Reports	Due to CMS 60 days after the end of a quarter.	One quarterly report per Federal Fiscal Year quarter during operation of the demonstration; the report for the fourth quarter of each year will serve as the annual progress report.
Final Report	Due to CMS 180 days after the end of the demonstration.	One final report.