

PHARMACY PLUS

A DEMONSTRATION PROGRAM UNDER SECTION 1115

Created by:



Centers for Medicare & Medicaid Services
Center for Medicaid and State Operations

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PHARMACY PLUS

A DEMONSTRATION PROGRAM UNDER SECTION 1115

Table of Contents

I. GENERAL DESCRIPTION	5
II. ASSURANCES	6
III. STATE-ONLY FUNDED PHARMACY PROGRAMS	7
IV. PROGRAM ELEMENTS	10
V. BUDGET NEUTRALITY	17
VI. EXPENDITURE AUTHORITY	19
VII. EVALUATION	20
VIII. ADDITIONAL REQUIREMENTS	21
ATTACHMENT 1	22
ATTACHMENT 2	23

PHARMACY PLUS

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Purpose and Application Instructions

Purpose:

- Remove barriers to pharmacy coverage for Medicare beneficiaries who are age 65 or older or expenses, e.g., Qualified Medicare Beneficiaries (QMBs) and Specified Low-income Medicare Beneficiaries (SLMBs)] who have not been determined eligible for full Medicaid benefits. Low-income is defined as having income at or below 200 percent of the Federal poverty level (FPL).
- Increase pharmaceutical coverage in the state.
- Promote flexibility for states that seek to provide pharmacy coverage.
- Reduce the administrative burden on states by providing a streamlined demonstration application.
- Provide guidance on key program design, cost containment, and budget requirements, such as:
 - benefit package
 - use of private sector pharmacy benefit management approaches
 - cost sharing
 - coordination with private insurance payers
 - data and budget worksheets needed to assure budget neutrality
- Increase the speed of the Federal review.

Features:

- Electronic application format with pop-up instructions for easier submission of essential program information.
- Structured series of check-off options to be selected by the states.
- Simplified submission of data using an Excel template.
- Model special terms and conditions of approval that support pharmacy expansions.

Application Submission Instructions:

This application has been written to read as a document prepared by the applicant including assurances to CMS by the applicant. The Pharmacy Plus Demonstration Template is a check-off application to guide and streamline the application process. Applicants should complete the check-off application and the budget shell and submit these items to CMS. The items within a shaded box are instructions to the user, and should be deleted prior to submission (with the exception of the “Pharmacy Plus” title). Please insert page numbers into the completed application document. The sample Special Terms and Conditions of Approval document should be excluded. We recommend that the applicant complete the check-off application in conjunction with technical assistance from CMS Central Office and Regional Office staff.

Submit the check-off application and the budget shell in hard copy and electronic copy using

1) mail hard copy original to:

Deirdre Duzor/Larry Reed,
Pharmacy Team
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services
Mailstop S2-08-07
7500 Security Blvd
Baltimore, MD 21244
(410) 786-7456

2) e-mail to:

PharmacyPlus@cms.hhs.gov

The creation of this template has been through a team effort from the Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations. Any questions relating to the template may be directed to (410) 786-7456. In the voicemail, leave a detailed message with your name, organization, phone number (with area code), e-mail address, and the type of information you would like to receive.

PHARMACY PLUS

A DEMONSTRATION PROGRAM UNDER SECTION 1115 Pharmacy Plus Application

The State of _____, Department of _____ proposes an 1115 demonstration Proposal entitled _____, which will extend pharmacy services and related medical management interventions to _____ individuals at or below _____ percent of the Federal poverty level (FPL).

I. GENERAL DESCRIPTION

This demonstration will extend pharmacy coverage, via authority under section 1115 of the Social Security Act (the Act), to individuals in a fashion that furthers public, private, and individual fiscal responsibility. The demonstration is designed to increase the extent of pharmacy coverage in the state by assisting low-income Medicare beneficiaries who are age 65 or older or who have a disability who have high drug costs. The demonstration offers assistance by 1) providing access to prescription drugs and related services, 2) assisting individuals with high premiums/cost sharing for private coverage for prescription drugs, or 3) providing [wraparound](#) pharmaceutical coverage to bring private sources of pharmacy coverage up to the level of the Pharmacy Plus benefit coverage. The proposed program also ensures access to primary care to complement and assist in the management of the enrollee's pharmacy services. An important element in Pharmacy Plus is the use of competitive private sector approaches, such as benefit management, to provide more cost effective, modern prescription drug benefits in Medicaid

Individuals eligible for the proposed program include those who are Medicare beneficiaries, who have not been determined eligible for [traditional Medicaid](#) benefits, whether or not they are eligible for [Medicare Savings programs](#) under Medicaid (which pay Medicare premiums, and in some cases, Medicare cost sharing expenses, e.g., QMBs and SLMBs) and/or people with a disability. Cost sharing - in the form of premiums, copayments, coinsurance, and deductibles - for the expansion population may differ from cost-sharing requirements for the regular Medicaid program.

The [budget neutrality](#) ceiling will be a single aggregate budget amount for the demonstration period. The state will be accountable for both expenditure and enrollment growth in the population subject to the budget neutrality ceiling which includes both the demonstration enrollees and the budget neutrality [impacted population](#). The demonstration impacted population is that current law Medicaid eligibility group whose costs will be captured in order to measure budget neutrality.

The demonstration will operate for _____ years, beginning approximately _____.

II. ASSURANCES

Each of the following items are checked to indicate an assurance:

- A. _____ **Primary care coordination.** The demonstration includes a mechanism to direct demonstration enrollees who access services to sources of primary health services. Such primary care will include, but is not limited to, medical management related to prescription and non-prescription pharmaceutical products. The state assures that those individuals who do not have access to primary care as Medicare beneficiaries will have access to primary care services. More information about this requirement is provided in [Section V, Part I](#).
- B. _____ **Benefits, access to services, and cost sharing.** The benefits and rights of the state plan eligibility groups, except for restriction to choice of providers as provided through a section 1115(a)(1) waiver of section 1902(a)(23) of the Act through Pharmacy Plus, are as provided for in the state's Medicaid state plan, Title 42 of the Code of Federal Regulations, and Title XIX of the Social Security Act.
- C. _____ **Budget neutrality.** The Federal cost of services provided during the demonstration will be no more than 100 percent of the expected Federal cost to provide Medicaid services under current law without the demonstration. The benefits and rights of the state plan eligibility groups are not altered by this demonstration. An Excel budget worksheet is provided that includes the budget projections, with and without waiver cost estimates, information about covered individuals, trend rate information, and a narrative description of the calculations. More information about this requirement is provided in [Section VI](#).
- D. _____ **Public notice requirements.** The demonstration complies with public notice requirements as published in the Federal Register, Vol. 59, No. 186 dated September 29, 1994 (Document number 94-23960) and Centers for Medicare & Medicaid Service (CMS) requirements regarding Native American Tribe consultation. Provide information about this assurance in [Appendix 1](#).

III. STATE-ONLY FUNDED PHARMACY PROGRAMS

The following information is provided for current state-only funded pharmacy programs (Check all that apply):

A. _____ State program entirely subsumed into demonstration. A state-only funded pharmacy program named _____ currently exists, and it will be subsumed by the demonstration (Complete this section for each state program that will be entirely subsumed into the demonstration program. Provide as an attachment a description of the state-only funded program, including enrollee cost-sharing, benefit limits, wraparound coverage, and any other pertinent features).

1. Income level ceiling. The income level ceiling for participation is _____ percent of the Federal poverty level (FPL).
2. Program eligibility characteristics. In addition to income ceiling, the program eligibility parameters have the following further specifications:
 - a. _____ age group (describe):
 - c. _____ condition specifications (describe):
 - d. _____ other specifications (describe):
3. Benefit coverage scope. The scope of benefits covered under the program is:
 - a. _____ broad (such as the Medicaid package):
 - b. _____ narrow (such as limited to drugs to treat specific health conditions):
 - c. _____ other (describe):
4. _____ There are enrollee financial contributions, which include:
 - a. _____ premiums (describe):
 - b. _____ deductibles (describe):
 - c. _____ copayments/coinsurance (describe):
 - d. _____ other (describe):
5. This proposed demonstration will be an expansion of coverage compared to the current state pharmacy program through:
 - a. _____ expanding the scope of coverage (e.g., type or number of prescriptions available) (describe):
 - b. _____ expanding the pharmacy services available (e.g., by providing a pharmacy or nurse consultant who will provide additional management services)(describe):
 - c. _____ expanding the type of individuals eligible (describe estimates):
 - d. _____ expanding the number of individuals eligible (describe estimates):
 - e. _____ expanding funding to assist with premiums and cost sharing (describe):
 - f. _____ other (describe):
6. Annual cost. Currently the program expenditures are \$ _____ on an annual basis for the program.

7. Enrollment figures. Currently there are _____ enrollees in the program.
8. Average cost per enrollee/per month is \$ _____.

B. _____ State program partially subsumed into demonstration. A state-only funded pharmacy program named _____ currently exists, and will be **partially** subsumed by the demonstration (Complete this section for each state program that will be partially subsumed into the demonstration program. Provide as an attachment a description of the state-only funded program, including enrollee cost-sharing, benefit limits, wraparound coverage, and any other pertinent features).

1. Income level ceiling. The income level ceiling for participation is _____ percent FPL.
2. Program eligibility characteristics. In addition to income ceiling, the program eligibility parameters have the following further specifications:
 - a. _____ age group (describe):
 - b. _____ condition specifications (describe):
 - c. _____ other specifications (describe):
3. Benefit coverage scope. The scope of benefits covered under the program is:
 - a. _____ broad (such as the Medicaid package);
 - b. _____ narrow (such as limited to drugs to treat specific health conditions);
 - c. _____ other (describe):
4. _____ There are enrollee financial contributions, which include:
 - a. _____ premiums (describe):
 - b. _____ deductibles (describe):
 - c. _____ copayments/coinsurance (describe):
 - d. _____ other (describe):
5. This proposed demonstration will be an expansion of coverage compared to the current state pharmacy program through:
 - a. _____ expanding the scope of coverage (e.g., type or number of prescriptions available) (describe):
 - b. _____ expanding the pharmacy services available (e.g., by providing a pharmacy or nurse consultant who will provide additional management services)(describe):
 - c. _____ expanding the type of individuals eligible (describe estimates):
 - d. _____ expanding the number of individuals eligible (describe estimates):
 - e. _____ expanding funding to assist with premiums and cost sharing (describe):
 - f. _____ other (describe):
6. Annual cost. Currently the program expenditures are \$ _____ on an annual basis for the program.
7. Enrollment figures. Currently there are _____ enrollees in the program.

8. Average cost per enrollee/per month is \$ _____.

C. _____ State program not subsumed by demonstration. A state-only funded pharmacy program(s) named _____ currently exists, will not be subsumed by the demonstration, and will continue to operate during the Pharmacy Plus demonstration operation.

D. _____ No state funded pharmacy program currently exists. A state-only funded pharmacy program does not exist in this state.

IV. PROGRAM ELEMENTS

Population to Whom Eligibility is Expanded under this Demonstration

Individuals eligible for Pharmacy Plus include Medicare beneficiaries who are age 65 or older or who have a disability, whether or not they are eligible for [Medicare Savings programs](#) under Medicaid (which pay Medicare premiums, and in some cases, Medicare cost sharing expenses, e.g., QMBs and SLMBs) and/or people with a disability, who have not been determined eligible for full Medicaid benefits. States also may propose to extend the pharmacy benefit to persons age 65 and older who are not Medicare beneficiaries and to persons under age 65 who receive Social Security Disability Insurance (SSDI) but not Medicare (i.e., are in the 24-month waiting period for Medicare) or who have a disability as defined by the Supplemental Security Income (SSI) program.

A. Eligibility groups

1. _____ Aged individuals (65 and older)
 - a. _____ Medicare beneficiaries
 - b. _____ non-Medicare beneficiaries
 - c. _____ individuals with private pharmacy coverage (describe):
 - d. _____ other (describe):

2. _____ Individuals with Disabilities (ages _____ to _____)
 - a. _____ Medicare beneficiaries
 - b. _____ individuals with private pharmacy coverage (describe):
 - c. _____ SSDI beneficiaries in 24-month waiting period for Medicare
 - d. _____ lost SSDI due to earnings (disabling condition continues)
 - e. _____ could receive Supplemental Security Income if Federal eligibility rules used (for 209(b) states)
 - f. _____ other (describe):

3. _____ Other (describe):

B. Income groups

1. _____ percent of FPL is the ceiling for the demonstration expansion group for aged individuals. NOTE, the CMS proposed ceiling is 200 percent FPL or below. The current Medicaid state plan coverage percentage level for this group is _____ percent FPL (if group varies within the aged population, describe):

2. _____ percent of FPL is the ceiling for the demonstration expansion group for individuals with disabilities. NOTE, the CMS proposed ceiling is 200 percent FPL or below. The current Medicaid state plan coverage percentage level for this group is _____ percent FPL (if group varies within the disabled population, describe):

C. Income adjustments

1. _____ Income is adjusted
 - a. _____ in the same manner as in Medicaid for the _____ group
 - b. _____ in a different manner than in Medicaid (describe):
2. _____ income is not adjusted

D. Assets test (an assets test of some level is recommended)

1. _____ an assets test will apply. It is
 - a. _____ the same as the Medicaid assets test for the _____ group
 - b. _____ different from the Medicaid assets test (describe):
2. _____ no assets test will apply

E. Enrollment limit

1. _____ is the total number of enrollees permitted to enroll in the demonstration (describe how and why this number was chosen): The state should clarify whether enrollment limits are year-specific or if the enrollment limit is the maximum enrollment for the five years. (For example, the state intends that 50,000 will enroll and the cap starts whenever 50,000 people enroll; or the state intends that 50,000 will enroll in Year One, 55,000 in Year Two, 60,000 in Year Three, etc.)
2. _____ There will not be an enrollment ceiling
3. _____ The state will not utilize an enrollment ceiling initially, but will track budget neutrality and plans to utilize the enrollment ceiling at a later point in time (describe):

F. Pharmacy benefits package

Consistent with the pharmaceutical focus of Pharmacy Plus, the demonstration does **not** include non-pharmacy benefit changes (such as reducing Medicaid coverage for other services or reducing coverage for existing Medicaid populations). The challenge posed in Pharmacy Plus is to improve cost-effectiveness through maintaining the health status of individuals and managing medications more effectively. The drug rebate provisions of section 1927 of the Act are triggered by state payments for prescription drugs under the plan by operation of the Pharmacy Plus demonstration project, and thus, [rebates](#) may be collected from manufacturers for drugs provided to the expansion population. The Federal share of rebates paid will be returned to the Federal government.

The following describes the proposed benefits to be included in this demonstration (check all that apply):

1. _____ demonstration eligibility will be extended to those who have pharmacy coverage through private health insurance, and enrollees will receive:
 - a. _____ assistance with [private health insurance](#) cost sharing (see Section V.H.);
 - b. _____ [wraparound](#) services (See Section V.H.);
 - c. _____ other (describe and See Section V.H.):

2. _____ enrollees without private health insurance pharmacy coverage will receive prescription drug coverage as follows:
 - a. _____ the benefit package will be the same as in the Medicaid state plan for non-demonstration enrollees;
 - b. _____ the benefit package will differ from that in the Medicaid state plan for non-demonstration enrollees in that:
 - i. _____ certain classes of drugs will be excluded or limited (describe):
 - ii. _____ the number or frequency of prescriptions covered will be less than in the Medicaid state plan for non-demonstration enrollees (describe):
 - iii. _____ drugs covered only for specified conditions (describe):
 - iv. _____ other (describe):
 - c. _____ other (describe):
3. the state limits benefits to a financial ceiling per _____ of \$ _____ (describe):
4. _____ other (describe):

G. Pharmacy benefit management

Pharmacy Plus programs may use private-sector benefit management approaches consistent with the requirements of section 1927(d) of the Act (such as pharmacy benefit managers, preferred drug lists, prior authorization, pharmacist consultation, provider education, disease state management, and variable enrollee cost sharing) in order to more efficiently and effectively manage pharmaceutical costs and ensure that spending stays within the Federal budget neutrality cap. In accordance with Section 1927 of the Act, these benefit management approaches also may be extended to some or all of the existing Medicaid population, and the resulting savings used to assist in achieving budget neutrality. The demonstration will include pharmacy benefit management as follows:

1. _____ pharmacy benefit manager (describe):
 - a. _____ this is currently used in the state Medicaid program, will continue to be operated similarly, and it is currently under contract with _____;
 - b. _____ this is not used in the state Medicaid program and will be used only for demonstration enrollees;
 - c. _____ this will be introduced with the demonstration and will apply to both the demonstration and non-demonstration Medicaid population;
 - d. _____ other (describe):
2. _____ [prior authorization](#) consistent with Section 1927(d)(5) of the Act (describe):
 - a. _____ this is currently used in the state Medicaid program;
 - b. _____ this is not used in the state Medicaid program and will be used only for demonstration enrollees;
 - c. _____ this will be introduced as a state plan amendment with the demonstration and will apply to both the demonstration and non-demonstration Medicaid population

3. _____ [formulary or formulary exclusions](#) consistent with Section 1927(d)(4) of the Social Security Act (describe):
 - a. _____ this is currently used in the state Medicaid program;
 - b. _____ this is not used in the Medicaid program and will be used only for demonstration enrollees;
 - c. _____ this will be introduced as a state plan amendment with the demonstration and will apply to both the demonstration and non-demonstration Medicaid population;
4. _____ other (describe):

H. Coordination with other sources of pharmacy coverage – private, state, and Medicare Plus Choice plans

Coordination with and non-duplication of existing sources of health insurance is an important feature of the Pharmacy Plus Demonstration. It maintains the position of Medicaid as payer of last resort and provides an incentive for enrollees to continue to participate in private coverage, thus supporting the maximization of participation in [private insurance](#), employer sponsored insurance, COBRA, retiree health insurance plans, Medigap plans and Medicare+Choice plans. Pharmacy Plus is designed to work effectively with other Medicare pharmacy options.

The coordination and support can be:

- Payments made to private carriers or to enrollees made in lieu of direct coverage of pharmaceuticals under the Pharmacy Plus program; and/or
- In the form of providing wraparound pharmaceutical coverage to bring private sources of pharmacy coverage up to the level of the Pharmacy Plus benefit coverage.

In this demonstration, the following approaches will apply (check all items that apply – Also, See Section V.F.1.):

1. _____ Subsidies/cost sharing assistance for private health insurance coverage will be provided under the demonstration, and is clarified in the submitted budget neutrality information. The process for providing the subsidy will be described in the operational protocol and CMS approval of the payment methodology and amount will be requested. Subsidies/incentives will be provided for enrollees to maintain coverage of the following:
 - a. _____ Private health insurance coverage (describe):
 - b. _____ Medigap (describe):
 - c. _____ Medicare-endorsed pharmacy discount cards. The demonstration includes financial contribution towards the drugs purchased using the card (describe coordination with the card and contribution to the purchase);
 - d. _____ other (describe):

2. _____ Pharmacy coverage will be provided to enhance other sources of pharmacy coverage, such as state programs, Medicare+Choice and private sources of coverage in a wraparound fashion in order to encourage participation in existing public and private sources of care (describe):
3. _____ Other (describe):
4. _____ Third Party Liability will be collected in the demonstration in the following manner (describe):
5. _____ Third Party Liability will not be collected in the demonstration because:
 - a. _____ individuals with other pharmacy coverage are excluded;
 - b. _____ other (describe):
6. _____ Coordination with other sources of coverage is not part of this demonstration because: _____.

I. Primary care coverage and related medical management (check all that apply)

The demonstration includes a mechanism to ensure that demonstration enrollees have access to primary care health services that will assist with medical management related to pharmacy products prescribed. These aspects of the demonstration will be implemented as follows:

1. _____ Demonstration enrollees who have a source of coverage for primary care (for example, Medicare coverage) will use their primary care providers to coordinate the pharmacy benefit (describe):
2. _____ Demonstration enrollees who do not have a source of primary care coverage will receive primary care services through the demonstration as follows:
 - a. _____ A primary care benefit the same as that in Medicaid will be provided (describe):
 - b. _____ A limited primary care benefit of _____ number of visits per _____, which entail the following services will be provided by _____ practitioners: _____;
 - c. _____ Primary care access will be ensured by connecting clients to primary care sources for care in the community (e.g., Federally qualified health centers/rural health clinics, Ryan White providers, Indian Health Services facilities, Veterans' Affairs clinics, etc.) If the above is checked, the following must be checked and completed:
 - i. _____ state to work with Primary Care Associations to facilitate access to services;
 - ii. _____ geographic breakdown of FQHC services provided that

- iii. _____ pharmacy and state written materials for demonstration participants include names, locations, and phone numbers of community sources of primary care;
 - iv. _____ oral counseling by pharmacists to include information on accessing primary care;
 - v. _____ Other (describe)
3. _____ Other (describe):

J. Premiums and cost sharing information (check all that apply)

Flexibility to include cost sharing, similar to that found in employer sponsored private health insurance coverage, is an important feature of the Pharmacy Plus Demonstration. Enrollee cost sharing can be in the form of annual or monthly premium assessments, per-prescription copayment requirements, coinsurance, deductibles, and coverage limits. Cost sharing helps the state to operate a budget neutral program and encourages personal responsibility and involvement of enrollees in their health care. States may require that cost sharing be met by demonstration participants (i.e., those in the [expansion population](#)) in order to receive benefits under the program. Cost sharing may be used to reduce program costs by requiring enrollee payments. To encourage the use of generic drugs and to discourage the use of costly drugs for which there are lower cost alternatives, Pharmacy Plus encourages states to use a three-tier system of copayments. Cost sharing models used in Pharmacy Plus may be designed to protect people with most severe illnesses or disabilities by offering “stop-loss” protection against the cumulative impact of copayments and deductibles

- 1. _____ The proposed program will include enrollee cost sharing (enrollment fees, premiums, copayments, coinsurance, deductibles, etc.):
 - a. _____ Enrollment fees will be required and are _____ every enrollment period of _____ months. If the fees vary according to individual FPL, specify below (describe):
 - b. _____ Premiums will be required:
 - i. _____ Premiums are tiered or charged according to a sliding fee schedule that is _____ attached or _____ described below:
 - ii. _____ Premiums are fixed in the amount of \$ _____ per person on a _____ monthly basis, _____ annual basis, or _____ other (described):
 - iii. _____ Other (describe):
 - c. _____ Copayments and Coinsurance:
 - i. _____ three-tiered copayment system (describe):
 - ii. in the amount of _____ per prescription; or
 - ii. _____ Enrollees will have different co-payments for single source, branded multi-source, and generic drugs, according to the following schedule (describe):

- iii. Brand name: \$ ____ per prescription or ____ percent of the cost;
- iv. Branded multi-source: \$ ____ per prescription or ____ percent of the cost;
- v. Generic: \$ ____ per prescription or ____ percent of the cost.

d. ____ Deductibles (describe):

e. ____ Cost sharing requirements will vary with utilization (i.e., premiums, copayments, and coinsurance)

i. ____ Cost sharing amounts/requirements will decrease as individuals use more services (describe):

ii. ____ Cost sharing amounts/requirements will increase as individuals use more services (describe):

iii. ____ Other (describe):

2. ____ The proposed program will not include enrollee cost sharing that differs from that in the Medicaid state plan.

3. ____ The proposed program will include enrollee cost sharing stop-loss protections (describe):

4. ____ Other (describe):

K. The demonstration will deliver services in the following manner (check all that apply)

1. ____ Services will be delivered through private health insurance coverage.

2. ____ Services will be delivered fee-for-service through this demonstration.

3. ____ Services will be delivered through a system other than fee-for-service through this demonstration (describe):

4. ____ Services will be delivered through this demonstration using the same network of providers that deliver comparable services to Medicaid beneficiaries.

5. ____ Services will be delivered through this demonstration using a subset of providers that deliver services to Medicaid beneficiaries.

6. ____ Services will not be delivered by providers that serve Medicaid beneficiaries (describe how providers will be selected):

7. ____ Other (describe):

V. BUDGET NEUTRALITY

The Federal costs of services provided during the demonstration will be no more than 100 percent of the expected costs of providing Medicaid services under current law without the demonstration. A new population that would otherwise not be eligible for Medicaid will be able to obtain prescription drugs paid for by Medicaid. While the demonstration includes individuals who are not otherwise eligible for full Medicaid coverage, this new population could become eligible for full Medicaid coverage over the life of the demonstration through deterioration in their health status and reduced income due to high medical expenses. Federal payments will be provided for the Pharmacy Plus costs incurred for the demonstration population to the extent that Federal Medicaid payments to the state do not exceed what would otherwise be paid.

The groups subject to budget neutrality - called the impacted population - are those expected to generate savings for the state because participants in Pharmacy Plus will incur less costs and remain healthier, thereby creating a delay in the need for full benefit Medicaid, in effect, be diverted from becoming eligible for full Medicaid eligibility. While the expenditures for these groups are included in budget neutrality, the benefits of the existing Medicaid eligibility groups are not to be altered. Cutbacks in eligibility for existing Medicaid eligibility groups covered under the state's Medicaid Plan cannot be used as a source of savings for purposes of meeting budget neutrality. Savings that do not reduce benefits or limit eligibility but are achieved through better management of pharmacy services to existing Medicaid populations may be considered in the budget neutrality calculations. States should include only direct Medicaid costs and savings in their budget neutrality calculations.

The [Terms and Conditions of Approval](#) will specify that demonstrations must be in compliance with Federal law and regulation related to sources and uses of Medicaid financing. In its budget neutrality calculations, the state should be able to demonstrate the impact of any recent changes to Medicaid law and regulation in its without-waiver and with-waiver calculations. For example, a state with an approved Upper Payment Limit plan, entitled to a transition period, under regulation, must demonstrate how the excess payments made under the UPL plan will be phased out during the waiver.

The Terms and Conditions of Approval will specify the aggregate financial ceiling for future expenditures for which Federal financial participation (FFP) will be available. Under the aggregate ceiling methodology the state and Federal authorities must reach agreement prior to demonstration approval on cost and eligibility trend rates. The trend rates will then be in place in the budget ceiling during the demonstration.

The attached budget shell relies upon a credible methodology that estimates a budget neutral program. When a Pharmacy Plus demonstration entirely or partially subsumes a state-only funded pharmacy program, the state must provide documentation as to how Medicaid expenditures will be reduced under the demonstration (compared to the "without demonstration" levels) and how budget neutrality will be achieved. The attached budget shell _____ was used in the development of the [budget neutrality ceiling](#).

- A. **Impacted budget neutrality population.** Table V.1 identifies the Medicaid population groups that are included in the budget neutrality calculation (i.e., the impacted population).

Table V.1 (check all groups that apply):				
Population	All (1)	Institutionalized (2)	Community Dwelling (3)	Other (described): (4)
Aged				
Blind/Disabled Adults				
Blind/Disabled non-Adults				

- B. **Costs.** The state estimates the services cost of this program will be \$_____ over its _____ year demonstration period.

Refer to attached Excel spreadsheet for details.

VI. EXPENDITURE AUTHORITY

The following authority is needed for this demonstration under costs not otherwise matchable (item is checked to verify the request):

- A. _____ Section 1115(a)(1) authority of the Social Security Act is requested to enable the state to restrict freedom of choice of provider through a method such as pharmacy benefit management.
- B. _____ Section 1115(a)(2) authority of the Social Security Act is requested for the following expenditures to be made under the _____ demonstration (which are not otherwise included as expenditures under section 1903) for the period of the demonstration to be regarded as expenditures under the Title XIX program.

Expenditures for extending pharmacy benefits and _____ for _____ individuals _____ at or below _____ percent of the Federal poverty level (FPL) who are Medicare low-income aged and disabled, who are not otherwise Medicaid eligible under the state plan except for Medicaid coverage of Medicare premiums or cost sharing.

In addition, the following will not be applicable in this demonstration:

- *Premiums and Cost Sharing under Section 1916*: To permit fixed premiums, and cost sharing that is more than nominal, to be imposed on and collected from demonstration participants.
- *Amount Duration and Scope of Services under Section 1902(a)(10)(B)*: To permit the state to offer demonstration participants benefits that are not equal in amount, duration and scope to traditional Medicaid beneficiaries.
- *Retroactive Eligibility under Section 1902(a)(34)*: To permit the state not to offer demonstration participants retroactive eligibility.
- *Premiums under Section 1902(a)(14)*: To permit the state to impose on and collect premiums from demonstration participants in excess of those that would be permitted under section 1916.

VII. EVALUATION

The purpose of Pharmacy Plus is to expand coverage of a prescription drug benefit to Medicare low-income aged and disabled, and, by so doing, to divert or defer entry by these individuals into the Medicaid program. Budget neutrality is a feature of these demonstrations and is designed to track the overall cost and savings of the program. However, it is important to evaluate these demonstrations in other than budgetary terms. To understand how effective the program is for individuals, provide a description below of the state context of the program, the goals for the program, and how the program's success will be evaluated. In addition, CMS intends to conduct an independent evaluation of several of the Pharmacy Plus demonstration projects.

Included as an Attachment to the Application are the following:

- A. _____ Current State Context. Provide an assessment of the current pharmacy coverage status of individuals in the state which includes summary information of individuals whose incomes are at or below 200 percent FPL who:
1. _____ do not have private insurance or other coverage of pharmaceuticals;
 2. _____ have private insurance that covers pharmaceuticals;
 3. _____ are in the state only funded pharmacy program;
- B. _____ The state's goal for increasing pharmacy coverage to the population targeted by the demonstration, including:
1. _____ the state's demonstration hypothesis;
 2. _____ the state's execution of the hypotheses via the demonstration project operation.

VIII. ADDITIONAL REQUIREMENTS

In addition to the above requirements, the state agrees to the Pharmacy Plus Model Special Terms and Conditions (STCs) of Approval, and agrees to prepare the [Operational Protocol](#) document as described in the Model STCs. During CMS's review and consideration of this demonstration request, using the Model STCs, we will work with CMS to develop STCs that are specific to this request that would become part of the approval of demonstration authority.

This demonstration proposal is submitted to CMS on ____ - ____ - ____.

Date

Name of Authorizing Official, Typed

Name of Authorizing Official, Signed

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A DEMONSTRATION PROGRAM UNDER SECTION 1115

Attachment 1

Public Notice ([Assurance D Description](#))

Provide a description of the public notice process for Pharmacy Plus, including varying activities and stakeholder groups included in each:

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A DEMONSTRATION PROGRAM UNDER SECTION 1115

Attachment 2

DEFINITIONS

Budget Neutrality –The policy for Section 1115 demonstrations under which the Federal costs of services provided during the demonstration will be no more than the expected Federal cost to provide Medicaid services without the demonstration.

Budget Neutrality Ceiling –An expenditure limit, negotiated between the state and CMS, placed on the amount of FFP available to a state under the demonstration. The expenditure limit for Pharmacy Plus waivers is calculated using the aggregate method. The aggregate expenditure limit is calculated as a fixed amount that does not vary based upon enrollment changes in the state.

Private Health Insurance - Group health plan coverage and health insurance coverage as defined in section 2791 of the Public Health Services Act.

Expansion population - Individuals eligible for benefits under the state Pharmacy Plus demonstration program who are not enrolled in the regular Medicaid program.

Traditional Medicaid benefit – The Medicaid benefit package available to individuals who are eligible under the state plan for Medicaid without the Pharmacy Plus waiver.

Impacted population - The Medicaid eligibility group or groups whose Medicaid costs are included in the budget neutrality cap. Under Pharmacy Plus, the state is expected to achieve savings from this group because of the diversion from the regular Medicaid program of a proportion of the expansion population.

Enrollee Cost Sharing – Premium charges, enrollment fees, deductibles, coinsurance, copayments or other similar fees that the Pharmacy Plus enrollee is responsible for paying. Cost sharing for Pharmacy Plus enrollees can deviate from requirements in Medicaid and can be used to reduce program costs by requiring participant payments, encouraging the use of non-brand drugs, and can vary to moderate out of pocket burdens for high utilizers.

Enrollment Ceiling -- A number limit on demonstration program enrollment. States may use an enrollment ceiling to limit the numbers of individuals enrolled in the demonstration so that financial risk for demonstration costs is minimized. States may not enact an enrollment ceiling for the non-demonstration Medicaid program.

Drug Rebates - The quarterly payments made by the pharmaceutical manufacturer to the state

Medicaid agency, as calculated in accordance with section 1927 of the Social Security Act and the provisions of the agreement between the manufacturer and the Secretary. States can receive rebates for pharmaceutical products in Pharmacy Plus as long as a state payment is made for the drug.

Wraparound Coverage - Pharmacy Plus coverage of services not covered under a beneficiary's private health insurance. Examples of wraparound coverage include a Pharmacy Plus program paying for drugs not covered by private insurance, a Pharmacy Plus program covering an amount of drugs in excess of that covered by private insurance (for example, if the private insurance coverage includes three prescriptions per month, Pharmacy Plus could pay for additional prescriptions); and Pharmacy Plus coverage when a private insurance financial benefit is exceeded.

Terms and Conditions of Approval - A document produced by CMS which provides conditions which states must follow in order to receive approval of their Pharmacy Plus waiver.

Operational Protocol - A stand-alone document that reflects the operating policies and administrative guidelines of the Pharmacy Plus waiver.

Prior Authorization – Requiring approval of the drug before it is dispensed as defined in 1927(k)(6) of the Act.

Formulary or Formulary Exclusions - A list of prescription drugs developed in accordance with 1927(d)(4) of the Social Security Act.

Medicare Savings Programs - Medicare beneficiaries who have low income and limited resources may receive help paying for their out-of-pocket medical expenses from their State Medicaid program. There are various benefits available to "dual eligibles" who are entitled to Medicare and are eligible for some type of Medicaid benefit.