

INNOVARX INC.

**COST-SHARING
COLLECTION POLICY &
FINANCIAL HARDSHIP
WAIVER PROGRAM**

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INTRODUCTION & POLICY STATEMENT

As patient cost-sharing expenses increases, the corresponding obligation of a pharmacy to ensure compliance with all rules applicable to collection of patient cost-sharing responsibility increases as well. Medicare, Medicaid and PBMs all have various rules and requirements pertaining to cost-sharing collection. This program is meant to provide parameters for when InnoRx Inc. (the “Pharmacy”) may grant waivers to patients of cost-sharing responsibility.

The Pharmacy is committed to complying with federal and state laws and PBM requirements concerning collection of patient cost-sharing responsibility. At the same time, the Pharmacy recognizes that lack of access to healthcare, including potential life-saving drugs, is an all-too-common issue, and is committed to an ethical, compassionate and socially just policy of providing access to high-quality health care to all patients. The Pharmacy has encountered situations in which patients are unable to pay cost-sharing obligations for medications because of financial hardships. In some situations, patients fail to pay cost-sharing obligations despite the Pharmacy’s good faith collection efforts. To address these situations, the Pharmacy has created this Cost-Sharing Collection Policy & Financial Hardship Waiver Program. This Program will provide policies, procedures and forms to be utilized when (i) collecting patient cost-sharing responsibility; and (ii) waiving such cost-sharing responsibility due to the patient’s financial hardship.

BACKGROUND

The Pharmacy’s obligations with respect to collection of patient cost-sharing responsibility arise from multiple sources, including, but not limited to: federal and state law, Medicare and Medicaid rules and regulations; and third-party payor (such as PBMs) contractual obligations found in pharmacy provider agreements and manuals. These obligations are discussed below.

As a starting point, the general rule is simple: the Pharmacy must collect patient cost-sharing responsibility. This is something that is required by all commercial and governmental third-party payors, subject to the exceptions discussed below.

Indeed, except under certain circumstances, waivers of patient cost-sharing obligations, such as deductibles and copayments are not permitted because such waivers misrepresent the Pharmacy’s actual charge and may result in false claims. Failure to collect patient cost-sharing responsibility creates significant legal risk for the Pharmacy: the United States Office of Inspector General has indicated that granting routine waivers of Medicare/Medicaid patient cost-sharing responsibility may violate the Federal Anti-Kickback Statute. Similarly, third-party payors, such as PBMs, consider routine waiver of patient cost-sharing responsibility to be a breach of the Pharmacy’s contractual obligations, and may deny claims for the which patient cost-sharing responsibility is not properly collected, and subject the pharmacy to further sanctions.

There are, however, exceptions to this rule, to the extent that the patient is unable to afford his or her cost-sharing responsibility. Accordingly, this Cost-Sharing Collection Policy & Financial Hardship Waiver Program (the “Program”) sets forth procedures that the Pharmacy and its personnel will follow regarding collection of cost-sharing responsibility and before any cost-sharing obligation is waived. Generally speaking, under this Program, the Pharmacy may waive a patient’s cost-sharing obligation only after the patient demonstrates a financial hardship.

To the extent that a waiver is not granted, the Pharmacy will and must employ good faith efforts to collect all patient cost-sharing responsibility amounts.

POLICY & PROCEDURES

1. Definitions

In this Program, the following terms shall have the following meanings:

“Application” means the form entitled Financial Hardship Waiver Application. Patients must complete the Application to request a financial hardship waiver. The Application is attached as Exhibit “A.”

“Cost-Sharing Obligations” means payment obligations, including copayments, deductibles, and coinsurance, required under a patient’s arrangement with the patient’s third-party payor. Also referred to as “cost-sharing responsibility”.

“Federal Poverty Guidelines” or “FPG” are measures of poverty issued yearly by the Department of Health and Human Services in the Federal Register. Often referred to as the “federal poverty level.” The current FPGs are listed in Exhibit “D.”

FHW Affidavit is the form entitled Financial Hardship Waiver Affidavit, which a patient may complete to be pre-qualified for a Financial Hardship Waiver. For a waiver to be granted, a patient must still complete a FHW Application and submit supporting documentation. The FHW Affidavit is attached as Exhibit “B.”

FHW Officer is the person at the Pharmacy who is responsible for reviewing applications and determining whether to grant a financial hardship waiver. _____ will serve as the FHW Officer under this policy.

“Financial Hardship Waiver” or “FHW” means a waiver of a cost-sharing obligations provided by the Pharmacy to a patient because the patient demonstrated a financial need, in accordance with applicable law and third-party payor/PBM requirements.

2. Policies

Policy Regarding Routine Waivers. Routine waiver of patient cost-sharing responsibility is strictly prohibited by Medicare regulations and the terms of third-party payor/PBM agreements and provider manuals. Every waiver must be carefully considered and assessed on a case-by-case basis. If a waiver is granted, it must be done in accordance with the terms of this Program. A waiver cannot in any way be funded by a third-party program, although the Pharmacy may legitimately participate in copayment coupon or rebate programs, subject to applicable law and third-party payor/PBM requirements.

Policy Regarding Advertising of Waivers. Advertising or promoting waiver of patient cost-sharing responsibility is likewise strictly prohibited by Medicare regulations and the terms of PBM agreements and provider manuals. The Pharmacy, as such, will not advertise or otherwise promote the waiver of patient cost-sharing responsibility, and Pharmacy personnel are strictly prohibited from doing so. Pharmacy personnel may not initiate a discussion of the patient’s inability to pay their cost-sharing responsibility. Prior to dispensing medication, Pharmacy personnel must provide patients with an estimate of the patient’s cost-sharing obligation. If a patient then volunteers that he or she cannot afford to pay the patient cost-sharing responsibility, Pharmacy personnel should direct the patient to submit a FHW Application and forward the Application for the FHW Officer’s review. Only the FHW Officer may authorize a waiver, after consideration of the patient’s Application and supporting documentation. A patient may be, in the interim, be pre-qualified for a waiver if completing a FHW Affidavit, so as to allow the patient to receive his or her medication. After dispensing the medication, Pharmacy will document the requested waiver and submission of a FHW Affidavit and FHW Application.

Policy Regarding Medicaid Enrolled Patients. Under New Jersey State and federal law, Medicaid patients may not be denied their medications due to inability to pay patient cost-sharing responsibility. New Jersey State Medicaid Program guidance has interpreted this to mean that a pharmacy may not dispute or challenge a Medicaid enrollee’s statement that he or she cannot afford to pay patient cost-sharing responsibility. Accordingly, to the extent that a Medicaid enrollee indicates financial inability to pay his or her patient cost-sharing responsibility, the

Pharmacy must dispense the medication. A notation should be made in the patient's file to the effect that the patient indicated inability to pay patient cost-sharing responsibility.

3. Financial Hardship Waiver Procedure

Various third-party payors (such as PBMs) and the Medicare Program may have different requirements for granting hardship waivers. Below, however, are generally accepted policies and procedures for granting hardship waivers. If a specific payor has a different policy, substitute procedures may be necessary.

FHW Application. When a patient requests a financial hardship waiver, the Pharmacy will require the patient to complete and submit an application entitled Financial Hardship Waiver Application. If the patient requests an Application, Pharmacy personnel may email, fax, mail, or hand deliver the application to the patient. The patient must provide all documentation requested by the Application to be eligible for a Financial Hardship Waiver. Once an Application has been authorized, a new Application and supporting documentation is not necessary in each instance of a prescription being dispensed, but patients may be asked to sign a receipt of non-payment of cost-sharing responsibility due to a waiver being granted. A template receipt is attached as Exhibit "D".

Expiration; Up to Date Information. Upon receipt of the Application, the Pharmacy will inform the patient of the patient's responsibility to notify the Pharmacy of any changes to the patient's financial circumstances. The Pharmacy may rely on the documentation submitted by the patient for 12 months, unless the patient notifies the Pharmacy of any changes to his or her situation. At the expiration of the twelve-month period, if the patient requests that the Financial Hardship Waiver be renewed, the Pharmacy will request that the patient completes a new Application and provide updated documentation.

Documentation Supplementing the Application. Once receiving an Application with supporting documentation, Pharmacy personnel do not need to request further applications and/or documentation in every instance of dispensing medication. The Pharmacy will request certain documentation in support of an Application, including tax returns, bank statements and/or other evidence of the patient's financial need, which may include evidence of (i) homelessness; (ii) enrollment in Women, Infants, and Children (WIC) programs; (iii) receipt of food stamps; (iv) participation in a subsidized school lunch program; (v) participation in an unfunded state or local assistance program; (vi) residence in low income, subsidized housing; and/or (vii) other evidence of financial need, such as pay stubs or medical bills.

Eligibility Criteria for Financial Hardship Waivers. The FHW Officer will review the submitted documentation and determine, based on the full picture offered by the supporting documentation, whether the patient meets the criteria for a financial hardship waiver. The basis for any determination will be documented and kept in the Pharmacy's records. The eligibility criteria for financial hardship waivers are as follows:

- Full Waiver: The patient is eligible for full waiver of the patient's cost-sharing obligation if the patient's gross family income is less than or equal to the applicable FPG. Under such circumstances, the patient may receive a full waiver.
- Partial Waiver: If the patient's gross family income is greater than the applicable FPG, but less than or equal to two times the applicable FPG, the Pharmacy may reduce the patient's cost-sharing obligations. The amount waived will depend upon the particular patient's circumstances. If the patient's gross family income is greater than two times the applicable FPG, the Pharmacy will presume that the patient is not eligible for patient assistance unless (i) the patient's family has unreimbursed medical expenses that exceed 20% of its gross family income or (ii) the patient demonstrates the existence of other extraordinary circumstances that justify a financial hardship waiver. Under such circumstances, the FHW Officer may grant a partial waiver of the patient's cost-sharing obligation.

- **Extenuating Circumstances:** The FHW Officer has the authority to grant a full or partial waiver in the event the FHW Officer determines that such a waiver is justified by other extenuating circumstances applicable to the patient's financial situation. The basis for any determination shall be thoroughly documented in the Pharmacy's records. Additionally, to the extent that the FHW Officer has reason to believe that there is a good faith reason as to why a patient cannot provide supporting documentation, or if obtaining the supporting documentation would place the patient in threat of danger (i.e. domestic abuse), the FHW Officer may exercise discretion to verify the patient's financial circumstances through other means.

Provision of Financial Hardship Waivers. If the patient meets the eligibility criteria, the FHW Officer shall have sole authority to authorize a financial hardship waiver. The FHW Officer may also determine that a financial hardship waiver is unnecessary or inappropriate in a particular case. For example, the FHW Officer may decide that a financial hardship waiver is inappropriate because the patient falsified documentation or because the evidence of financial need is unreliable. The Pharmacy will promptly notify the patient of the FHW Officer's determination regarding the patient's Application.

Documentation. The Pharmacy will maintain copies of all Applications and supplemental documentation submitted by patients. The Pharmacy will document and maintain records concerning (i) the amount of a waiver provided to a patient and (ii) the basis for the Pharmacy's decision.

Yearly Review of Financial Hardship Waivers Granted. Each calendar year, the FHW Officer will evaluate the number of patients receiving financial hardship waivers from the Pharmacy, and review Application and Application procedures to ensure compliance with all applicable laws and obligations of the Pharmacy.

4. Procedure for Waivers Following Good Faith Collection Efforts

The Pharmacy may write off the cost-sharing obligation of a patient who does not qualify for a financial hardship waiver (including patients who do not provide supporting documentation for Applications or do not meet any exceptions to the need to provide documentation) only if (i) the patient's cost-sharing obligation remains unpaid after 120 days and (ii) the Pharmacy exercised and documented the following collection efforts:

- **Initial Invoice** - After the Pharmacy provides dispenses a medication to a patient, the Pharmacy will issue to the patient an invoice detailing the amount of the patient's cost-sharing obligation.
- **Second Invoice** - If the patient fails to pay the cost-sharing obligation within 30 days, the Pharmacy will send to the patient a subsequent statement detailing the patient's outstanding balance.
- **Telephone Contact and Third Invoice** - If the cost-sharing obligation remains unpaid after 60 days, the Pharmacy will send a third billing statement. Within 10 days following the date of the letter, the Pharmacy will contact the patient by phone. Phone calls will be made until affirmative contact is established with the patient or the patient's representative. During the phone call, Pharmacy personnel will (i) collect information concerning the reason for non-payment, (ii) solicit an agreement for a specific payment plan, and/or (iii) offer to provide an Application. If the patient submits an Application, the Pharmacy will promptly notify the patient of the FHW Officer's determination. If the application is denied, or the patient does not submit an application, the Pharmacy will continue efforts to collect the patient's cost-sharing obligation.
- **Fourth Invoice** - If the patient's obligation remains unpaid after 90 days, the Pharmacy will send a fourth billing statement.

All invoices, telephone and in-person contacts regarding the patient's cost-sharing obligation will be documented in the patient's billing file. If a patient's cost-sharing obligation remains unpaid after 120 days, the FHW Officer will review the documentation regarding the Pharmacy's collection efforts. The FHW Officer may then determine whether the Pharmacy will continue collection efforts, turn the account over to a collection agency, bring a

collection lawsuit, refuse to provide products and services to the client in the future, or write off the obligation. The FHW Officer may write off the obligation as long as the good faith collection efforts listed above are clearly documented in the patient's file.

EXHIBIT “A”
FINANCIAL HARDSHIP WAIVER APPLICATION

InnovaRx Inc.
Financial Hardship Application for Waiver of Cost-Sharing

InnovaRx Inc. (the “Pharmacy”) abides by its legal and third-party payor contractual obligations to collect patient cost-sharing amounts. Recognizing that circumstances may arise where an individual is unable to pay their cost-sharing responsibility, we have adopted a policy of screening requests for cost-sharing waivers. To do this, we must ask for certain financial information. All information will be held confidential according to our privacy policy.

Please note that all actual requests for a cost-sharing waiver are to be considered on an individualized basis. If and once a waiver has been granted, you may be asked to sign a receipt in each instance that the Pharmacy dispenses medication to you, confirming that your cost-sharing obligation has been waived based upon the information provided in and with this application, and that the information remains true at the time of each instance where medication was dispensed. To the extent that your financial situation changes, and a waiver is no longer necessary, you are asked to inform the Pharmacy of such occurrence. This application is valid for a period of one year, at which point a new application, if necessary, must be submitted and reviewed.

Patient Name: _____ Date of Birth: _____

Number of People in House: _____ Married (Y/N): _____ Number of Dependents: _____

Monthly Household Income: _____ Monthly Expenses: _____

Any patient applying for financial hardship copayment waiver should provide the following documents:

1. Copies of the last 3 payroll check stubs (or copies of unemployment, disability payment stubs, etc.)
2. Copies of the last 2 month’s bank statement
3. Copy of previous year’s tax return

Are there any unusual Financial Circumstances, Demands for Financial Resources or other Supporting Circumstances?

Please explain (e.g. unemployment, homelessness, enrollment in financial assistance or food support programs [WIC, SNAP; subsidized lunch programs], medical bills, credit card debt, etc.). Attach additional documentation as it applies to your situation.

I _____ understand that I am seeking a waiver of my cost-sharing obligation based on financial hardship. I hereby certify that due to my current financial circumstances, I am unable to pay my prescription cost-sharing obligation.

I attest that the information set forth above and/or attached to this application as supporting documentation is true and accurate to the best of my knowledge.

Patient's Signature: _____ Date: _____

FOR THE PHARMACY'S INTERNAL USE ONLY

Date Received Back From Patient: _____

Account Number: _____

Reviewed By: _____

Application Approved/Denied: _____

Comments:

Signature: _____ Date: _____

EXHIBIT “B”
FINANCIAL HARDSHIP WAIVER AFFIDAVIT

PATIENT AFFIDAVIT OF FINANCIAL HARDSHIP

STATE OF NEW JERSEY)
) ss:
 COUNTY OF _____)

_____, being duly sworn, deposes and says:

1. I am a patient of InnovaRx Inc. I make this affidavit in connection with my application for a financial hardship cost-sharing waiver.
2. My household financial information, as of the date of this affidavit, is as follows:

Monthly Income (after payroll deductions)	Amount	Monthly Expenses (not including payroll deductions)	Amount
Employment	\$	Mortgage/Rent	\$
Unemployment/Severance	\$	Auto/Transportation	\$
Self-Employment	\$	Non-reimbursed work expenses (e.g., parking, tools)	\$
Interest/Dividends	\$	Utilities (e.g., water, light, gas)	\$
Pension/Disability	\$	Medications	\$
Child Support/Alimony	\$	Childcare	\$
Short-Term Disability	\$	Child Support/Alimony	\$
Long-term Disability	\$		\$
Rental Income	\$		\$
Other Income	\$	Other Expenses (e.g., credit card debt)	\$
Total Average Income	\$	Total Average Expenses	\$

Dated: _____ By: _____

(insert name below signature)

EXHIBIT “C”
FINANCIAL HARDSHIP WAIVER RECEIPT

InnovaRx Inc.

I _____, confirm that on _____, I received the following medications:

I confirm that no cost-sharing obligation was paid pursuant to the waiver previously granted to me by the Pharmacy, and all information provided by me to the Pharmacy in connection with such waiver remains valid and up to date and/or otherwise meets all criteria for a financial hardship waiver.

Patient's Signature: _____

Date: _____

EXHIBIT “D”
FEDERAL POVERTY GUIDELINES

Attach the current Federal Poverty Guidelines issued by the Department of Health and Human Services for the applicable calendar year. The FHW Officer should verify that the current year’s guidelines are attached before using this Program for financial hardship determinations.