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# Report on Client Safety

## Health Canada's Non-Insured Health Benefits Program

MAY 2008

Canada

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MAY 2008

*Health Canada is the federal department responsible for helping Canadians maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit. We work with the provinces and territories to ensure our health care system serves the needs of Canadians.*

Published by authority of the Minister of Health.

Également disponible en français sous le titre :

*Rapport sur les améliorations apportées à la sécurité des bénéficiaires par le programme des Services de santé non assurés de Santé Canada, Mai 2008*

This publication can be made available on request on diskette, large print, audio-cassette and braille.

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HC Pub.: 3550
Cat.: H34-160/2008 (Print)
ISBN: 978-0-662-05637-9 (Print)
Cat.: H34-160/2008E-PDF (Web site version)
ISBN: 978-0-662-48379-3 (Web site version)

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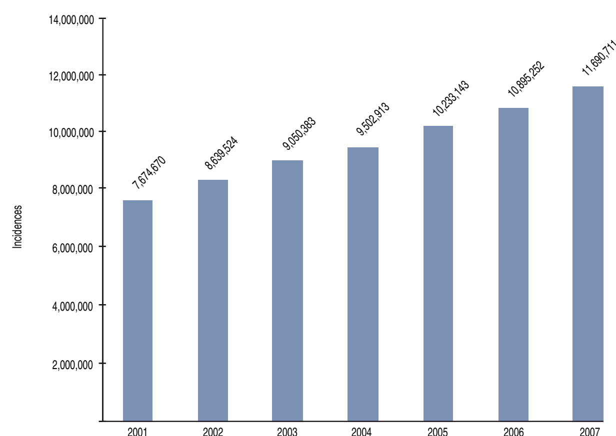
## Introduction

Health Canada's Non-Insured Health Benefits (NIHB) Program provides a limited range of medically necessary goods and services to eligible First Nations and Inuit clients. The Program is part of Health Canada's First Nations and Inuit Health Branch (FNIHB). The overarching goal of this Branch is to address the gap in health status that exists between First Nations and Inuit and other Canadians. NIHB does not provide prescription medications directly to clients. The Program, like other public and private drug plans, relies on physicians and other authorized prescribers to issue prescriptions and on pharmacists to dispense drug medications based on professional judgement. NIHB, with the assistance of a third party claims processing contractor, reimburses pharmacists for the cost of drugs as well as a fee for professional dispensing services. Eligible drug benefits are 100% covered for clients.

In 2007, the NIHB Program processed 13.8 million pharmacy claim lines[1]. Figure 1 demonstrates a steady increase in demand for prescription medications. This increase is in line with the population growth among First Nations and Inuit in Canada, which is approximately double the national rate. Of these requests, 11.7 million were approved, 660,000 were approved but reversed because they were never received by clients (i.e. not picked up) and 1.5 million were rejected either because the request was outside the mandate of the Program or because of client safety concerns.

This report provides an update on the Non-Insured Health Benefits Program's efforts in the area of client safety. It is a follow up to NIHB's February 2007 Client Safety Report.

### Figure 1 – NIHB paid claim lines by calendar year [1]




[1]A claim line represents a transaction request on the Program's electronic claims processing system. Many prescriptions contain multiple prescription drug requests and, therefore, generate multiple claim lines

## NIHB's Four Pillars of Client Safety

The evidence suggests that a vast majority of NIHB clients use the prescription drug benefits in an appropriate way. Inappropriate use of prescription medications under the Program continues to be very low. Despite the low incidence rate of inappropriate use of prescription medications, the Program continues to place a high priority on addressing those cases of concern and on enhancing the safe use of prescription medications under the NIHB Program.

The four pillars to NIHB's approach to client safety are:

1. **Warning messages** to pharmacists regarding drug interactions and repeat prescriptions;
2. **Rejection messages** to pharmacists regarding client drug therapy history, and the requirement to contact NIHB's Drug Exception Centre;
3. **Client and Program level trend analysis** of prescription drug use; and
4. The creation of an **independent expert advisory committee** to provide input, evaluations and recommendations for improvements to the Program.

As described throughout this report, the NIHB Program is beginning to see positive impacts as a result of key interventions under these pillars.

### Pillar 1

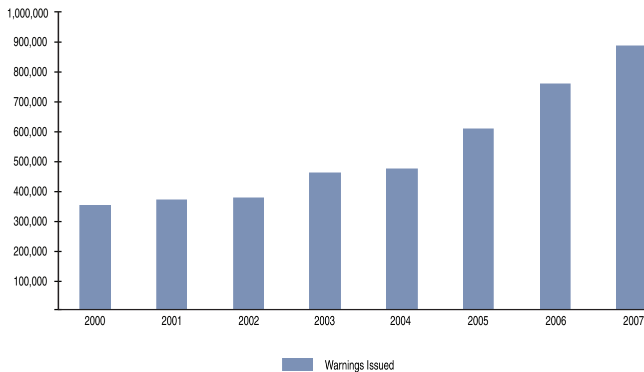
### *Warning messages to pharmacists*

Communication between the NIHB program and front-line pharmacists is essential in protecting client safety. NIHB has implemented a number of significant changes to enhance the important relationship between the Program and pharmacists. NIHB has been part of an industry-wide system since the early 1990's that allows the Program to send messages electronically in real-time to pharmacists at the point-of-sale to warn them about potential client safety issues including drug interactions and repeat prescriptions. The full list of NIHB warning codes is set out in Appendix 1. Certain warning messages also require the pharmacist to report back with specific codes that give the Program information about the actions they have taken related to the warning code received. A list of these response codes is included as Appendix 2.

Warning messages are important tools that supplement pharmacists' professional judgement at the point-of-sale. The NIHB Program actively monitors the number of pharmacy claims that are flagged with warning messages or rejected by this system.

Figure 2 shows the number of warning messages sent by the NIHB Program to pharmacies across the country since 2002. Over the past number of years the Program has increased its interventions with pharmacists significantly. The information provided via these warning messages greatly improves the range of information available to pharmacists and, as a result, enhances their ability to exercise their professional judgement.

**Figure 2 – NIHB warning messages over time [2]**




[2]2007 figures are based on NIHB transactions during the calendar year from January 1 to December 31. Any differences in yearly figures reported in the 2006 Client Safety Report reflect the use of a sample of 126 days from the same period in successive calendar years in that report. The figures presented in this Report represent actual transactions completed in each calendar year.

When pharmacies are found to be overriding warnings frequently, concerns will be raised by the Program. If the pattern continues, the pharmacy may be audited to ensure that client safety and the Program's financial integrity are not being compromised.

**Action:** 880,641 warning messages to pharmacists in 2007.

**Result:** Pharmacists armed with important information to enhance client safety.

NIHB able to actively monitor pharmacists' overrides of these messages.

516,990 of these prescriptions (59%) were not filled during 2007.

### New warning message for opioids, benzodiazepines and methadone

In April of 2006, the NIHB Program took an additional step to improve accountability and client safety. A special warning message was established to respond to the clinical evidence with respect to the health risks associated with the misuse of specific drugs of concern. These drugs include opioids (such as morphine, codeine, and oxycodone which are used to relieve pain), benzodiazepines (so-called "minor" tranquillizers, sleep aids and anti-anxiety medications) and methadone (a long-acting synthetic opioid used to treat opioid addiction or pain).

In designing the new warning message, it was important to recognize that all of these drugs have clinically valid applications. For example, opioid treatments are crucial in pain management for patients suffering from terminal cancer and palliative conditions. Therefore, the new warning message was designed to focus attention on cases where there were concerns about potential misuse, and where continued utilization was difficult to justify.

The new warning message, called the "NE" code, addresses situations where clients access:

- 3 or more active prescriptions for benzodiazepines, opioid-based drugs, opioids in combination with 3 or more benzodiazepines;

or

- a prescription for methadone in association with opioid-based drugs.

The new warning provides a message to pharmacists indicating that potential misuse of prescription drugs should be explored. It is one more tool to supplement their professional judgement and to protect client safety. Other federal, provincial and territorial drug benefit plans have taken an interest in NIHB's new warning message and may follow NIHB's lead in developing similar warning messages in the future.

In September 2007, the NIHB Program changed the NE code from a simple warning message to a warning that requires pharmacists to reply back to the Program with a response code. This added feature ensures that, if pharmacists override the NE code, they must document the rationale for doing so by sending a response code back to the NIHB Program. Pharmacists are expected to retain the supporting information justifying the response in case of a clinical or administrative audit. An assessment of the impact of the NE code is provided in the Evaluating Outcomes section of this report (figure 6).

**Action:** New point-of-sale warning code to alert pharmacists of potential misuse of opioids/benzodiazepines and/or methadone that must be responded to for billings to be processed.

**Result:** Reductions in the number of clients claiming multiple opioids, benzodiazepines or methadone in association with another opioid-based drug.

**Action:** A new requirement for pharmacists to respond back to the Program on actions taken in the face of possible misuse of opioids/benzodiazepines and methadone.

**Result:** Greater transparency and documented responses by front-line pharmacists when the possibility of misuse of drugs of concern is raised by the Program.

## Pillar 2

### *Rejection messages regarding drug therapy history*

#### Special approvals required for patterns of concern

The NIHB Program also provides rejection messages to pharmacists when a client's claims history indicates potential misuse or overuse of a range of prescription medications. These rejection messages are different from the warning messages described in Pillar 1. It is not possible to override these messages or to provide an electronic response code. Instead when a rejection message is received, a pharmacist must contact NIHB's Drug Exception Centre, a national toll-free call centre. The Drug Exception Centre will provide more information to the pharmacist about the situation and follow up with the prescribing physician before the Program will authorize payment for the drug in question. The NIHB Program reserves the right to refuse payment for medications that cannot be justified when there is evidence that suggests client safety may be negatively affected.

**Action:** Development of rejection messages to reflect client claims history.

**Result:** A more rigorous approval process for patterns of concern in exceptional cases.

#### Maximum allowable quantities for acetaminophen and acetaminophen-based opioids

Over the past number of years, the Program has improved its sensitivity to situations where clients may be accessing prescriptions to the same drug via multiple sources. As a result of new sensitivities built into the electronic processing system, client claim requests will generate warning messages to alert pharmacists about potential duplicate therapies. When maximums are exceeded, a pharmacist will receive a message from the Program requiring them to consult with NIHB's Drug Exception Centre to verify the claim.

Prior to January 2005, NIHB applied maximum allowable rules to acetaminophen products that contained codeine, such as Tylenol 2 and 3. In January 2005, NIHB expanded system sensitivities to detect when maximum allowable dose limits were exceeded for all acetaminophen-based opioids products (e.g. Percocet and Tylenol 4). These measures are intended to build a firewall around medications most often subject to misuse.

As of January 1, 2007, the Program expanded the NIHB system's maximum allowable sensitivities to apply to all acetaminophen-based products. Clients are often unaware of the long-term consequences of commonly available acetaminophen-based products. Serious negative health effects can result from prolonged use, including serious liver damage if recommended dosages are exceeded. This further enhancement protects the safety of clients beyond the focus of the initial intervention.

Changes made since 2004 have resulted in a quadrupling of rejected claims where maximum daily doses would have been exceeded.

In 2004, NIHB rejected 73 claims when maximum allowable quantities were exceeded. In 2006, with the expansion of the maximum allowable rules to all acetaminophen containing opioids, 222 claims were rejected. In 2007, the Program rejected a total of 291 claims for acetaminophen or acetaminophen containing opioids

**Action:** Closer monitoring of acetaminophen and/or acetaminophen-based opioid drugs and special approvals required when maximums are exceeded.

**Result:** Rejected claims have quadrupled since 2004.

#### Maximum allowable quantities for meperidine (Demerol)

Based on the impact of the maximum allowables initiative, the NIHB Program also changed the benefit status of a prescription medication called meperidine (Demerol). This product is a strong opioid and should only be used for a short period of time. Long-term use may lead to toxic effects, as well as addiction. To ensure the appropriate use of meperidine (Demerol), the Program established a maximum allowable quantity in December 2007. The utilization rates of meperidine (Demerol) as a result of this restriction will be reported in the next Client Safety Report.

**Action:** Closer monitoring of meperidine (Demerol) and special approvals required when maximums are exceeded.

**Result:** Anticipated increases in rejected claims and early identification of inappropriate use of Demerol.

## Pillar 3

## *Client and Program level trend analysis*

### Client Level Analysis and Follow-up with Health Care Providers

The Program has developed a methodology that allows NIHB staff to identify clients at highest potential risk for misuse of benzodiazepines and/or opioid-based products. This approach has been reviewed and endorsed by NIHB's Drug Use Evaluation Advisory Committee (see Pillar 4).

Client profiles identified through this process are reviewed by NIHB pharmacy consultants, all of whom are licensed health care professionals. When concerns are flagged, and where the NIHB Program has the consent of the client to do so, the NIHB Program will follow up directly with health care professionals serving the client. Since November 2004, the Program has made approximately 1,100 interventions with both physicians and pharmacists involved in the prescribing and dispensing to clients who may be at risk. These interventions have been well received by health care professionals and have led to changes in utilization patterns.

**Action:** Ongoing monthly reviews of anonymized client profiles by NIHB pharmacy consultants

**Result:** Over 1,100 interventions with pharmacists and physicians since 2004

### The Prescription Monitoring Program

In an effort to improve communication with health professionals and to add an extra element to its approach to client safety, NIHB is developing a Prescription Monitoring Program (PMP) which focuses on the questionable use of benzodiazepines and opioids.

The PMP will complement existing activities and will promote the optimal use of medications by allowing the Program to enhance its interventions when drug use patterns of concern are observed. Variables like the number of physicians visited ("doctor shopping") and the number of NE warning codes generated will flag clients for enrolment into the PMP. Enrolment may restrict clients to specific physicians and require clients to have future claims verified and authorized by a pharmacist at NIHB's Drug Exception Centre. If clients or their health care providers cannot provide evidence to support the continuation of the drug therapy in question, the Program will reserve the right to refuse payment for the medications requested.

The first phase of the PMP was launched in Alberta in January of 2007. At present, there are 32 clients registered in Alberta, 7 of whom have a physician restriction. It is expected that the PMP can be expanded to Nova Scotia in 2008.

**Action:** Establishment of a Prescription Monitoring Program for clients with drug use patterns of concern.

**Result:** Improved monitoring and tighter approval process for clients with the highest risk of drug misuse.

### Program level analysis, identification of issues and adjusting program requirements

NIHB also actively analyses broad patterns of utilization, prescribing, and dispensing on an on-going basis. This work is conducted by a team of licensed pharmacists and experts in data analysis. Once patterns are identified, the Program intervenes to prevent the recurrence of inappropriate prescription drug use. For example, drugs subject to overuse/misuse have had their listing status changed from "Open-Benefit" to "Limited-Use Benefit" (with special approvals required) or, in certain circumstances, have been removed from the approved drug benefit list entirely. In addition, the Program releases periodic bulletins to health providers to ensure that they have access to the information they need to serve NIHB clients well. These bulletins are available on-line at the following address:

http://www.hc-sc.gc.ca/fnih-spni/pubs/drug-med/2006_11_due-um/index_e.html._

NIHB staff are also in regular contact with their federal, provincial and territorial counterparts who operate similar drug benefit plans to share best practice knowledge across jurisdictions.

**Action:** Ongoing Program level analysis and improvements.

**Result:** Ongoing review of drug utilization patterns.

Analysis and early identification of trends.

## Pillar 4

### *NIHB's Drug Use Evaluation Advisory Committee*

In order to further strengthen client safety initiatives, the Program established the NIHB Drug Use Evaluation Advisory Committee in 2003. The purpose of this committee is to provide independent expert advice to promote improvements in health outcomes of First Nations and Inuit clients through effective use of medications. This Advisory Committee is composed of various health care professionals, including a number of First Nations physicians. It meets four times per year to review drug-use trends for NIHB clients and make recommendations for program interventions, and to follow-up on specific issues.

In particular, the Committee has focussed on reviewing a wide range of drugs (30 studies complete/ongoing) with a view to improving client safety. The results of these analysis are sent periodically to health professionals across the country through the Drug Use Evaluation Bulletin. In addition, on the advice of this Committee, the Program has sent letters raising concerns to top prescribers of benzodiazepines. Other contributions of the Committee include the development of the new NE code for opioids, benzodiazepines and methadone, as well as completed studies on asthma drugs, statin drugs for cholesterol and chronic obstructive pulmonary disorder. A full list of ongoing and complete studies is set out in Appendix 3. The Program will continue to look to the Committee to provide valuable advice on further enhancements to client safety.

**Action:** Regular meetings of an external expert advisory body to identify and evaluate emerging drug use issues

**Result:** 30 studies of specific drugs related to client safety. Enhanced information on client safety issues to health care professionals serving First Nations and Inuit

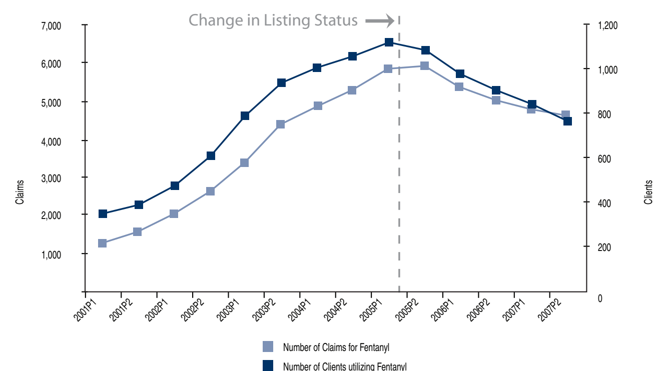
## Evaluating Outcomes

The Program is committed to measuring and demonstrating the impact of interventions to promote client safety. The advice of the Drug Use Evaluation Advisory Committee has been invaluable in helping NIHB develop a measurement methodology to produce useful data over the long term. In this regard, evaluations to measure the influence of three interventions are detailed below.

### Changes in benefit status: fentanyl (Duragesic)

In October 2005, the NIHB Program changed the benefit status of a prescription pain patch called fentanyl (or Duragesic). This product is a potent long-acting opioid product that was being requested in increasing amounts for a number of years. Evaluations concluding that this particular drug was subject to overuse prompted the Program to change fentanyl's benefit status from "Open Benefit" to "Limited Use". This change requires special authorization from NIHB's Drug Exception Centre before approvals can be granted. Claims data indicate that, since these restrictions were put in place, the Program has effectively reversed the inappropriate utilization trend for this particular drug (see Figure 3).

**Figure 3 – Impact of changing the listing status of Fentanyl (Duragesic)**




The Program is continuing to monitor use patterns of fentanyl (Duragesic) to ensure that clients with a legitimate need for this drug (chronic and cancer pain) continue to have appropriate access.

**Action:** Changes to access to the benefit status of the opioid-based drug fentanyl or Duragesic.

**Result:** In the second half of 2007, there were 1300 fewer claims for fentanyl than in the same period before the change in the listing status.

300 fewer clients accessed fentanyl in the second half of 2007 than before the change in listing status – a 29% reduction.

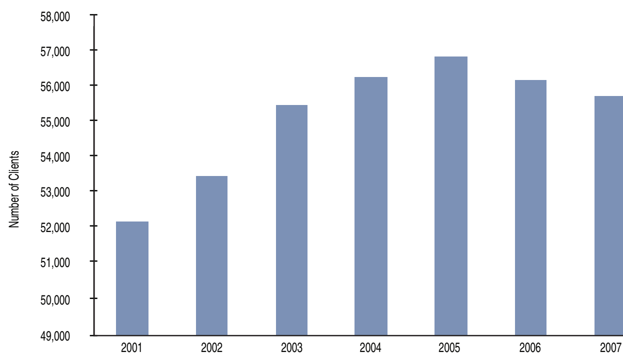
### Impacts of Program interventions on benzodiazepine use

The range of interventions highlighted in this document are aimed at reducing problematic drug use. One of the main areas of concern has been benzodiazepine use. This class of drug is meant to be a short-term remedy for individuals coping with anxiety or sleep problems. There is little clinical evidence to support long-term use of benzodiazepines.

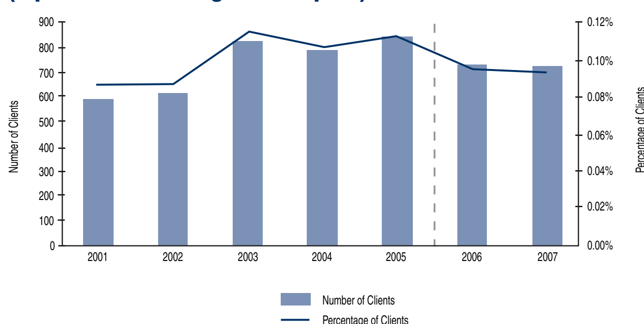
Physical addiction can often result from long-term use and can produce adverse health and social effects. Based on well-documented concerns, NIHB removed a number of long-acting benzodiazepines from its approved Drug Benefit List in September 2007. The use of long-acting benzodiazepines in the elderly is of grave concern because of the link to cognitive impairment and serious injuries as a result of falling accidents.

The NIHB Program has undertaken specific evaluations of trends in benzodiazepine use to measure the effectiveness of recent interventions. The number of clients accessing benzodiazepines, the number of claims approved and the number of clients exceeding the maximum recommended daily dose (equivalent to 40 mg per day of diazepam) all declined in 2007 (see figures 4 and 5). These trends are consistent with the general downward trend reported in the 2007 Client Safety Report.

### Figure 4 – Number of clients claiming benzodiazepines




### Figure 5 – Number of Clients exceeding the maximum recommended daily dose of the benzodiazepines (equivalent to 40 mg of diazepam)




**Action:** Removal of a number of long acting benzodiazepines from the NIHB approved drug benefit list.

**Result:** Reductions in the number of clients exceeding the maximum recommended daily dose of drugs in the benzodiazepine class.

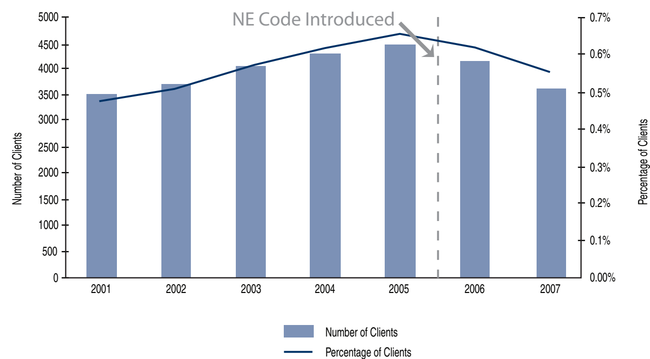
### Measuring the impact of the "NE Code"

To evaluate the impact of the "NE code", NIHB has measured the number and percent of clients who accessed three or more benzodiazepines, three or more opioids or opioids in conjunction with methadone treatment. Consistent with the numbers reported in the 2007 Client Safety Report, utilization of these medications at these thresholds of concern continued to decline in 2007 (see Figure 6).

Of note is the very low percentage of clients who have claimed these drugs of concern at these levels (a fraction of 1%).

### Figure 6 – Measuring the impact of the NE Code

**Number and percentage of clients claiming 3 or more benzodiazepines, 3 or more opioids, or opioids in association with methadone.**




**Action:** NE code to alert pharmacists of potential prescription drug misuse.

**Result:** Reductions in the number of clients claiming three (3) or more prescription drugs in the benzodiazepine category.

Reductions in the number of clients claiming three (3) or more prescription opioid drugs.

Reductions in the number of clients claiming opioids in addition to methadone treatment.

## Complementary community-level approaches

In addition to the NIHB interventions, the First Nations and Inuit Health Branch is actively working at the community level to promote healthy lifestyles and to prevent the misuse and abuse of prescription drugs. The Branch has initiated demonstration projects aimed at raising awareness of harm associated with prescription drug abuse and delivering evidence-based prevention strategies that will address prescription drug abuse. Linkages are being established among First Nations and Inuit communities, academic institutions, health care organizations and other local organizations. Intermediate results will provide a better understanding of how to design, integrate and implement effective intervention strategies that are culturally-specific and knowledge-based. The long term objective of the demonstration projects is to develop culturally appropriate, evidence-based prevention and promotion strategies that prevent the misuse and abuse of prescription drugs, leading to improved health outcomes for First Nations and Inuit people.

An evaluation tool has developed to generate community reports that describe the utilization of certain drugs within First Nations communities. These reports allow the NIHB Program to compare utilization rates across bands, regions and nationally. Results have been shared with interested First Nations stakeholders.

**Action:** Demonstration projects in First Nations and Inuit communities to promote healthier use of prescription medications.

**Result:** Improved understanding of the impacts of use of prescription drugs among First Nations and Inuit people.

**Action:** A new evaluation tool that generates community level reports.

**Result:** Closer attention to usage trends for a wide range of medications.

## Conclusion

The Non-Insured Health Benefits Program is taking an active, evidenced-based and measured approach to further develop client safety activities. This approach stresses the appropriate use of medications with a view to achieving the best possible health outcomes for First Nations and Inuit clients. Significant interventions are now in place. The Program is committed to monitoring and measuring the impact of these interventions and working with expert advisors, stakeholders and other key players to identify further improvements to the NIHB client safety regime.

With a First Nations and Inuit client base growing two times faster than the Canadian average, the Non-Insured Health Benefits Program has experienced yearly increases in utilization rates, particularly for prescription medications, the Program's most frequently used benefit. The Program has taken steps to confine and reduce the inappropriate use of medications. Consequently, although the utilization numbers for drugs of concern declined only slightly in the last year in sheer numbers, these reductions represent significant improvements to client safety when viewed in the larger context of client population growth.

The Non-Insured Health Benefits Program remains committed to ongoing evaluations of its client safety regime. The Program will continue to report on these issues on an annual basis by way of this report.

# Appendix 1

### NIHB Point-of-Sale Warning and Rejection Messages

| Message | Code* | Description |
|---|---|---|
| ***Drug to drug interaction potential*** | ***ME (hard)*** | ***Indicates that drug may interact with another current drug, based on an accurate days supply submission.*** |
| Duplicate Therapy | MX (soft) | Indicates that the client has received a drug from the same therapy class. |
| Duplicate Therapy Multi-Pharmacy | MZ (soft) | Indicates that the client has received a drug from the same therapy class; however, the original prescription was filled at another pharmacy. |
| ***Duplicate Drug*** | ***MW (hard)*** | ***Indicates that the client has received the same drug (same chemical entity) and has used less than 2/3 of the medication based on the days supply.*** |
| ***Duplicate Drug Multi-Pharmacy*** | ***MY (hard)*** | ***Indicates that the client has received the same drug (same chemical entity) and has used less than 2/3 of the medication based on the days supply; however the original prescription was filled at another pharmacy.*** |
| Potential Misuse of Prescription Drugs | NE (soft) | Indicates<br>• 3 or more benzodiazepines<br>• 3 or more opioids<br>• 3 or more benzodiazepines and 3 or more opioids<br>• methadone in combination with other opioid drugs |

* NB: the codes noted above are not acronyms; the letter codes are not initials for other terms

The codes and messages described in Table 1 in bold font denote "hard" edit rejection codes. Claims submitted through the NIHB Point of Sale system which prompt any of these four messages will not be accepted for payment. In order to submit the claim for payment, pharmacists who receive these rejection codes must provide an override code back to the NIHB Program to explain the action that they took, based on their professional judgement, in deciding to dispense the claim. In cases where pharmacists choose to override a rejected claim, the prescriptions are paid by NIHB.

# Appendix 2

### Pharmacy codes for overriding* NIHB rejection messages

| Code | Interpretation |
|---|---|
| UA | Consulted prescriber and filled Rx as written |
| UB | Consulted Prescriber and Changed Dose |
| UC | Consulted Prescriber and Changed Instructions For Use |
| UD | Consulted Prescriber and Changed Drug |
| UE | Consulted Prescriber and Changed Quantity |
| UF | Patient Gave Adequate Explanation, Rx Filled as Written |
| UG | Cautioned Patient, Rx Filled as Written |
| UI | Consulted Other Sources. Rx Filled as Written |
| UJ | Consulted Other Sources. Altered Rx and Filled |
| UN | Assessed Patient. Therapy is Appropriate. |
| MR | Replacement, Item Lost or Broken. |

* In order to override NIHB warning codes, pharmacists must report on their actions to NIHB by sending an override message that details the specific action taken as a result of the warning message.

# Appendix 3

### Drug Use Evaluation Advisory Committee reviews and ongoing analysis

| DUE Reviews Conducted to Date | Ongoing and Planned Analysis |
|---|---|
| • Diabetes medications | • Antibiotics |
| • Benzodiazepines | • Updated and standardized reporting on diabetic and antibiotic medication use |
| • Antidepressants in children and adolescents | • Diabetic test strips |
| • Opioids | • Anti psychotic medications |
| • Methylphenidate for ADHD | • Community and physician reports |
| • Biologics for Rheumatoid Arthritis | • Methadone |
| • Contraceptive Use | • Evaluations of various NIHB Program interventions |
| • Clopidogrel (Plavix) | • Chronic obstructive pulminary disease (COPD) |
| • Concurrent use of Cox IIs and proton pump inhibitors | • Thiazolidinediones (diabetes drugs) |
| • Folic acid and prenatal vitamins | |
| • Smoking cessation aids | |
| • Clients with more than 50 prescriptions in 90 days | |
| • Emergency dispensing trends in the Program | |
| • Statins | |
| • Acetaminophen | |
| • Drug use trends in seniors | |
| • Asthma | |
| • Cancer drugs | |
| • HIV/AIDS medications | |
| • Fentanyl patch | |
| • Evaluation of the proton pump inhibitors intervention | |

# Notes