

# 5 Health and Wellness: Nova Scotia Prescription Monitoring Program

# Summary

While some aspects of the Nova Scotia Prescription Monitoring Program are effective, there are significant weaknesses in the Program's control and monitoring processes that can allow abuse or misuse of prescription drugs to continue undetected. Improvements are needed to address these issues.

We found the Program's governance structure is adequate. Detailed oversight rests with the Prescription Monitoring Board; the Department of Health and Wellness is represented on this Board by two Department employees. The Board receives regular information from Medavie, the Program's contracted administrator. We are concerned that the Board appears to emphasize one aspect of its mandate, education, over active monitoring. The issues we identified during our audit show that the Board needs to do more to address its mandate related to promoting the reduction of abuse or misuse of monitored drugs.

While the Program's online system which pharmacists use to enter monitored drug prescriptions is a positive step, there are gaps in the system. Pharmacists can override the online system and dispense medication despite potential issues identified; the program does not track or monitor the results of these warnings. Additionally, monitored drugs dispensed to hospital inpatients or in emergency rooms are not entered in the online system and the Program has no information regarding these drugs.

The Program does produce regular reports to assess utilization of monitored drugs and individuals receiving prescriptions from multiple prescribers. However many situations identified in these reports are not followed up. We recommended the Program redesign its reports so that fewer items are identified, and most of those require further investigation. For those instances which were followed up, prescribers did not always meet Program deadlines for information. We also found the Program's medical consultant did not always review information in a timely manner and we recommended establishing deadlines which the medical consultant must meet.

We found Program staff do not document details of their review of drug utilization and multiple prescriber reports or the reasons for decisions reached. We identified many instances in which there was no evidence that appropriate action was taken when potential concerns were identified

Controls over the Program's duplicate prescription pads need improvement. We recommended that the Program establish processes to ensure pads which have been reported as lost, stolen or forged are marked as void in the online system immediately.



# 5 Health and Wellness: Nova Scotia Prescription Monitoring Program

# Background

- 5.1 The Prescription Monitoring Act was approved in October 2004; it was proclaimed along with the Prescription Monitoring Regulations in June 2005. A Prescription Monitoring Board (Board) was appointed to establish and operate the Nova Scotia Prescription Monitoring Program (Program). The Board reports to the Minister of Health and Wellness.
- 5.2 In 2005, Health and Wellness entered into an agreement with Medavie Blue Cross to administer certain provincial programs, including the Prescription Monitoring Program. As administrator, Medavie works with the Board to determine how the Program should function.
- 5.3 During 2010-11, the Program participated in several educational seminars and presentations and provided data on the prescribing and utilization of monitored drugs to various stakeholder groups including medical professionals, law enforcement and community groups. The Program's medical consultant is also available as a resource to prescribers.
- 5.4 The Program's objectives are "to promote (a) the appropriate use of monitored drugs; and (b) the reduction of abuse or misuse of monitored drugs." A monitored drug is defined as any drug that is a controlled drug in the schedules to the Controlled Drugs and Substances Act (Canada), with some exceptions.
- 5.5 The Board interprets its legislative mandate, including its mission, to be:
  - "educate prescribers, dispensers, and the general public on the appropriate use of monitored drugs;
  - collaborate and develop working partnerships with other key organizations in order to achieve the Program's objects; and
  - proactively share information in a timely and responsive manner to allow others to do their part in achieving the Program's objects." (Source: Program website)
- 5.6 The Prescription Monitoring Board's interpretation of its mandate focuses on the dissemination of information through trend analysis, education and communication. We interpret promotion as involving taking action to achieve improvements in the areas of appropriate use of monitored drugs and reduction of abuse and misuse.
- 5.7 The Program's monitoring activities not only promote the appropriate use of monitored drugs, but also help to reduce misuse and abuse. Both the drug utilization



- review and multiple prescriber reports achieve both of these objectives. We focused our audit largely on the monitoring activities the Board conducts, as these provided some coverage of all aspects of its mandate.
- 5.8 Prescriptions for monitored drugs are written on pre-numbered, duplicate prescription pads. The prescriber retains one copy of the prescription and the pharmacy retains the other copy.
- 5.9 The Program has an online prescription database. Pharmacists enter monitored drug prescriptions into the Program's online database before dispensing the drugs. This system also notifies pharmacists of potential issues such as a patient filling prescriptions for monitored drugs from several prescribers or a stolen prescription.
- 5.10 The database and its reports are intended to allow the Program to identify trends in the prescribing and utilization of monitored drugs and to intervene when necessary. Standard reports are generated which provide information on individuals who may be misusing or abusing monitored drugs. In some instances, prescribers receive letters asking for information regarding a prescription or the physician's prescribing practices. Responses are required within Program deadlines ranging between approximately two weeks and a month. Failure to provide a response can result in the prescriber being referred to the College of Physicians and Surgeons of Nova Scotia; the professional body responsible for regulating physicians in the province. These activities serve to address both the promotion and monitoring aspects of the Program's legislated mandate.
- 5.11 The Board has also established subcommittees.
  - The Drug Utilization Review Committee considers drug utilization data to monitor the prescribing and utilization of monitored drugs and to identify unusual and potentially inappropriate trends.
  - The Practice Review Committee provides peer review of physician's responses to Program inquiries regarding prescriptions.
- 5.12 The Program's volume and demand for its services have increased in recent years. The Program processed approximately 700,000 prescriptions in 2010-11, an increase of 36% since 2007-08. Prescribers, pharmacists, licensing authorities and law enforcement can request patient profiles from the Program outlining an individual's history of monitored drug purchases. The number of patient profile requests increased from 792 in 2007-08 to 1,643 in 2010-11.
- 5.13 The abuse of prescription opiate medication has received considerable media attention due to overdoses and deaths in the province attributed to monitored drugs in recent years. While the Program covers certain avenues to obtain monitored drugs, there are other legal sources that fall outside the Program, such as monitored drugs dispensed to hospital inpatients or through emergency rooms. Additionally, there are many potential illegal sources of monitored prescription drugs.



# Audit Objectives and Scope

- 5.14 In early 2012, we completed a performance audit of the Nova Scotia Prescription Monitoring Program to assess whether the Program adequately monitors the prescribing and utilization of monitored drugs and takes appropriate action when potential abuse is identified. We did not examine all the work completed by the Program. The specific education initiatives undertaken by the Program to promote appropriate use of monitored drugs are lower risk. We chose to focus our work on the Program's monitoring of the prescribing and utilization of monitored drugs as these were the highest risk areas. However, the monitoring activities the Program engages in not only help to reduce misuse and abuse, but also educate stakeholders and promote appropriate usage.
- 5.15 The audit was conducted in accordance with Sections 18 and 21 of the Auditor General Act and auditing standards established by the Canadian Institute of Chartered Accountants.
- 5.16 The objectives of this audit were to assess:
  - the adequacy of the Department of Health and Wellness' oversight of the Program;
  - compliance with the contract between the Province and Medavie Blue Cross to administer the Program;
  - the adequacy of the Board's governance of the Program;
  - whether the Program is adequately monitoring the completeness, accuracy and timeliness of monitored drug prescription information received from pharmacies;
  - whether the Program is adequately monitoring the prescribing and utilization of monitored drugs and taking timely and appropriate action when trends or possible abuses are identified;
  - whether the Program has adequate controls over the storage and issuance of duplication prescription pads; and
  - whether there is an adequate process to respond to lost, stolen or forged duplicate prescription pads.
- 5.17 Generally accepted criteria consistent with the objectives of the audit did not exist. Audit criteria were developed by our Office specifically for this engagement. These criteria were discussed with, and accepted as appropriate by, senior management at the Department of Health and Wellness and the Prescription Monitoring Program and Board.



5.18 Our audit approach included an examination of legislation and the Program's monitored drug prescription information. We tested compliance with selected policies and conducted interviews with management and staff. Our audit period covered April 1, 2009 to October 31, 2011.

# Significant Audit Observations

# Program Oversight

# Conclusions and summary of observations

The Prescription Monitoring Program's governance structure is adequate. Detailed oversight of the Program rests with the Board; two employees of the Department of Health and Wellness are Board members and can represent the Department's interests. Medavie Blue Cross administers the Program on behalf of the Board; we found the Board regularly monitors Medavie's compliance with its obligations. Although Health and Wellness told us that hospitals are supposed to review monitored drugs prescribed to inpatients and those in emergency, only one district health authority was able to provide the Prescription Monitoring Program with any information. We recommended this gap in reviewing legal sources of monitored drugs be addressed.

- 5.19 *Board structure* The Board is comprised of 10 members, including the registrar from each of the College of Physicians and Surgeons of Nova Scotia, Nova Scotia College of Pharmacists, and the Provincial Dental Board of Nova Scotia, plus one additional member appointed by each of these bodies, along with two public members appointed by Health and Wellness and two nonvoting members from the Department. During our audit period, the Board was missing one of its two public members.
- 5.20 The two Health and Wellness employees can provide input and represent the Department's interests; however, beyond this arrangement there is limited reporting between the Board and the Department. The Department receives information on the Program's activities and the utilization of monitored drugs in the Province through business plans and annual reports.
- 5.21 *Committee structure* The Board established the following committees to assist in administering the Program and identifying and evaluating possible abuse or misuse of monitored drugs.
  - An Executive Committee to discuss urgent matters that may arise between Board meetings
  - A Drug Utilization Review Committee to review aggregate monitored drug prescription data to identify potentially inappropriate trends
  - A Practice Review Committee to provide peer review of the responses to drug utilization review inquiries



- 5.22 We reviewed Board minutes and found that the Board is reviewing information received from its committees.
- 5.23 During our audit period, each committee had a full complement of members and was meeting at an appropriate frequency.
- 5.24 There was adequate attendance at meetings of the Board and Practice Review Committee; however attendance at Drug Utilization Committee meetings was poor. The Committee did not have a full complement of members at any of its ten meetings during our audit period. At three of those meetings, less than half of the committee members attended. The Board seeks practicing clinicians to participate as committee members and this can cause challenges since these individuals also see patients. Program management and the Board told us they are attempting to address this issue through recent membership changes.
- 5.25 Contract with administrator In 2005, the Department of Health and Wellness entered into a contract with Medavie Blue Cross (Medavie) to administer certain provincial programs, including the Nova Scotia Prescription Monitoring Program. The contract clause related to the Program is very brief and does not outline the responsibilities of each party. Instead, it calls for a separate agreement to document Medavie's service delivery obligations. Health and Wellness gave the Nova Scotia Prescription Monitoring Board responsibility for developing and monitoring these obligations. Although the Board developed a service obligation agreement with Medavie, Health and Wellness should have established the expectations of both parties before signing a contract. Failure to do so is a poor business practice; once a contract has been signed, there is no assurance government will be able to reach an agreement with an external service provider.
- 5.26 *Medavie's service obligations* The Board and Medavie signed a service obligation agreement outlining Medavie's responsibilities. The Board monitors compliance with the service obligations and legislative requirements through a report which Medavie submits at each Board meeting. Legislative requirements are also monitored through the Board's review of the Program's annual report. Overall, the Board is doing a good job of overseeing Medavie and the Program at a high level, however as discussed later, we are concerned that there are significant gaps in the Program's control and monitoring processes.
- 5.27 We did identify one instance of noncompliance with the service obligations; there is no ad hoc committee to review the list of monitored drugs. However the Board does discuss changes to the list at meetings as necessary. Management told us that this committee has not been established because only the Minister can approve changes to the monitored drug list, which is based on the federal Controlled Drugs and Substances Act and regulations. Any changes to federal act and regulations would be reflected in the list used by the province.



The Nova Scotia Prescription Monitoring Board and the Department of Health and Wellness should review and amend the service obligations agreement with Medavie Blue Cross to address any requirements which are no longer relevant.

# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. By the end of 2013, the three parties will review the Service Obligations Agreement in conjunction with changes made to move the prescription capture function into the provincial Drug Information System (DIS). This timing will ensure the Service Obligation Agreement does not include requirements that will be assumed by the DIS.

#### Nova Scotia Prescription Monitoring Board Response:

The NSPMP Board ("the Board") agrees with this recommendation and commits to collaborating with the Department of Health and Wellness (DHW) to review the Service Obligations Agreement by the end of 2013. The review process will take into account the functions and activities that will eventually be moved from the NS Prescription Monitoring Program (the Program) to the provincial Drug Information System (DIS) in 2013.

- 5.28 The Board completes an annual effectiveness survey to evaluate Medavie's performance against the Program's stated goals and objectives. We reviewed the survey results for 2009, 2010 and 2011; there were no issues identified with Medavie's performance.
- 5.29 Monitoring gap The Program is not responsible for monitored drugs provided to patients discharged from hospitals or emergency rooms. Health and Wellness management told us that hospitals are supposed to monitor utilization of these drugs. However, when the Program asked district health authorities across Nova Scotia to provide statistics on opiate use for patients in hospitals, only one district was able to provide this information. Although Regulations to the Prescription Monitoring Act state that prescriptions are not required on duplicate forms for those in hospital, this does not mean it is not necessary to supervise monitored drugs dispensed through hospitals.

#### Recommendation 5.2

The Department of Health and Wellness should require hospitals in the province to provide regular reports of monitored drugs dispensed to patients when discharged from hospitals or emergency rooms, either directly to the Department or to the Nova Scotia Prescription Monitoring Program.

# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation and will examine the business requirements for this reporting with the District Health Authorities (DHAs) – including costing – so reporting of monitored drugs provided to patients/individuals when they leave hospitals or emergency rooms is in place by 2014.



# Prescription Monitoring Information System

# Conclusions and summary of observations

The Program's online prescription information system provides pharmacies with information on an individual's utilization of monitored drugs, as well as data for further Program monitoring. Although the system is a positive step towards examining the use of monitored drugs, we identified areas in which improvements are required. Pharmacists can fill prescriptions for monitored drugs without immediately entering the prescription in the online system; in these instances, the information is sent to the Program within 30 days. As a result, information is not available in a timely manner and we recommended that all pharmacists be required to enter monitored drug prescription information in the online system as soon as possible. While the system notifies pharmacists of potential issues such as obtaining prescriptions from several physicians, the Program does not monitor the effectiveness of these notifications to assess whether they impact the potential abuse or misuse of monitored drugs. We found the Program relies on pharmacy audits to verify that prescription information was entered in the system accurately. However not all pharmacies have been audited and improvements are needed to audit processes.

- 5.30 Prescription Monitoring Program database The Prescription Monitoring Program has an online database which all pharmacies can access. When monitored drugs are dispensed, pharmacists enter the prescriptions into the database. The Program uses this information to monitor the prescribing and utilization of monitored drugs in Nova Scotia.
- 5.31 Response codes The database uses response codes to provide immediate feedback and information to pharmacists regarding patients and their prescriptions. Response codes vary and include indicators that a patient is deceased, or that a patient has submitted another prescription for a monitored drug within the last 30 days. When a response code is received, the pharmacist must use professional judgment to determine whether to dispense the prescription.
- 5.32 Although there could be many situations in which a pharmacist might appropriately dispense a monitored drug after receiving a response code, we are concerned the Program is not tracking whether prescriptions are dispensed or canceled based on the response code. While these prescriptions may be dispensed legitimately, the Program could be monitoring long-term trends related to response codes to attempt to identify pharmacies which fall outside the normal patterns of dispensing. The results of such monitoring could be used to further educate pharmacists and to assist with the reduction of abuse or misuse of monitored drugs.

#### Recommendation 5.3

The Nova Scotia Prescription Monitoring Program should monitor and assess action taken based on response codes as a means to identify pharmacies which may require further follow-up.



# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The Department, in collaboration with the Board, will direct the Administrator to identify interim options to monitor and assess actions taken on response codes sent to pharmacies. The Board will work with the Administrator to determine the feasibility of the options, select one, and implement it by the end of 2013. Note that in 2013 the DIS will assume the prescription capture functions for the Program, and monitoring and assessment of response codes will be part of the system functionality.

# Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation. Although the provincial DIS will eventually assume the prescription capture functions currently carried out by the Program, the Board will work in collaboration with the DHW to ensure the implementation, by the Administrator, as soon as reasonably possible, of quality assurance measures to monitor and assess actions taken on response codes to pharmacists.

- 5.33 Alerts The Program also issues alerts to pharmacies and physicians for various matters including stolen duplicate prescription pads and possible situations in which an individual tries to obtain monitored drug prescriptions from more than one physician. During our audit period, 18 alerts were issued, the majority of which related to stolen duplicate prescription pads. One alert during our audit period related to attempts to obtain monitored drugs from several prescribers.
- 5.34 Medavie regularly provides alert information to the Board. However, as with response codes, the Program does not monitor the effectiveness of the alerts it issues. Monitoring is important to confirm whether alerts are an effective tool to promote appropriate use and reduce misuse and abuse of monitored drugs.

#### Recommendation 5.4

The Nova Scotia Prescription Monitoring Program should monitor the effectiveness of its alerts to physicians and pharmacists and report the results to the Board.

#### Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The Department, in collaboration with the Board, will direct the Administrator to identify indicators that could be used to measure the effectiveness of alerts and propose options for measuring these indicators that can be implemented in 2013.

#### Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation and commits to working with the DHW in directing the Administrator to, with the assistance of experts, identify a mechanism and indicators for monitoring the effectiveness of its alerts to physicians and pharmacists and to commence measuring these indictors as part of its ongoing quality assurance activities in 2013.



5.35 Lack of timely information — Pharmacists are supposed to enter prescription information into the online system immediately. However, if the system is not available, the pharmacist is permitted to dispense the monitored drug provided the prescription is submitted to the Program within 30 days. When prescriptions are not entered immediately, resulting delays can reduce the effectiveness of the response codes sent to pharmacists. Potential issues, such as multiple prescriptions for the same monitored drug or a patient receiving monitored drug prescriptions from more than one physician, may not be identified until long after the medication has been dispensed. This problem could be avoided if pharmacists were required to enter information regarding monitored drugs dispensed when the system is not working as soon as the system becomes available.

#### Recommendation 5.5

The Nova Scotia Prescription Monitoring Program should require pharmacies to enter prescription information for monitored drugs dispensed when the system is not working as soon as the system becomes available.

# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The DIS will address this issue when it assumes the prescription capture functions for the Program. In the interim, the Department will direct the Board to require the Administrator develop and implement a policy that addresses this issue by the end of 2012. The Department will follow up with the Board in 2013 to ensure compliance.

#### Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation. Although the provincial DIS will eventually assume the prescription capture functions currently carried out by the Program and will address this matter, the Board will direct the Administrator to develop and implement an interim policy by the end of 2012.

- 5.36 Pharmacy audits In 2009, the Program began pharmacy audits to monitor the quality of prescription information received. If prescription information is not entered accurately or in a timely manner by pharmacists, this impacts the Program's ability to identify possible instances of inappropriate prescribing, abuse or misuse of monitored drugs. Pharmacy audits are primarily intended to ensure all prescriptions have been submitted to the Program. The audits also address whether all prescriptions in the online database are supported by original prescription slips, and whether detailed Program information agrees to original prescriptions. Program staff assess whether a pharmacy passes or fails an audit. The current pass rate is 90%; prior to 2011 it was 75%.
- 5.37 Each pharmacy is to be audited at least once every two years to determine if prescription information submitted is complete, accurate and timely. Our audit period covered 31 months and we found 31 pharmacies were not audited during that time. When the audit process was first implemented, scheduling was based on the Nova



Scotia College of Pharmacists' audit process because the Program obtained certain pharmacy information from the College. Management told us that the Program now obtains this information directly from the pharmacy, allowing the Program to set its own schedule. Management are hopeful this will allow the Program to meet its two-year target in the future.

#### Recommendation 5.6

The Nova Scotia Prescription Monitoring Program should conduct audits of all pharmacies registered with the Program at least once every two years.

# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation and notes that the Program already conducts audits of all registered pharmacies at least once every two years. The Department will direct the Board to monitor these audits to ensure compliance by 2013. The Department will follow up with the Board in 2013 to confirm compliance.

# Nova Scotia Prescription Monitoring Program Board Response:

The Board agrees with this recommendation. This policy is currently in place.

5.38 If a pharmacy fails its first audit, a second audit is completed. However, this covers the same overall time period as the first audit, and the results are considered in isolation from the initial audit. If the pharmacy passes the second audit, no further steps are taken. While testing additional sample items is a reasonable approach when issues are identified, the final audit conclusion should be based on all sample items tested throughout the period, and the determination of whether the pharmacy passes the audit should depend on the results of all items tested.

#### Recommendation 5.7

The Nova Scotia Prescription Monitoring Program should change its audit process to base final conclusions on all items tested during the audit period.

# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The Program has based its final audit conclusions on all items tested during the audit period. The Department will direct the Board to monitor these audits to ensure compliance by 2013. The Department will follow up with the Board in 2013 to confirm compliance.

#### Nova Scotia Prescription Monitoring Program Response:

The Board agrees with this recommendation and will ensure that the Administrator's audit process will include this methodology by the end of 2012.

5.39 We selected a sample of 20 audits in which the pharmacy received a failing score. We found nine of the 20 pharmacies failed two consecutive audits while three pharmacies failed three consecutive audits.



- 5.40 The Program may refer a pharmacy which fails an audit to the Nova Scotia College of Pharmacists. Six pharmacies included in our sample were referred to the College at some point during the Program's audit process. Three were referred after an initial audit, two were referred to the College after failing the second audit, and one was referred after failing a third consecutive audit.
- 5.41 The decision to refer a pharmacy to the Nova Scotia College of Pharmacists following a failed audit will depend on various factors and sometimes involves discussion with the College. Our sample included four instances in which follow-up audits were conducted after a pharmacy had been referred to the College of Pharmacists. In three of these cases, the pharmacy received a passing score on the subsequent audit. Although this relates to a small number of cases, referring pharmacies to the College of Pharmacists appears to be an effective way to improve compliance with Program requirements.

# **Prescription Monitoring Processes**

# Conclusions and summary of observations

The Program has processes to monitor the prescribing and dispensing of monitored drugs but there are considerable weaknesses that allow potential abuse or misuse to continue undetected. Drug utilization review and multiple prescriber reports are not effective; each report identifies many possible issues but a very small number are followed up. There is no support to confirm that all situations identified in the reports were appropriately reviewed; we could not tell why cases were closed or flagged for further investigation. We identified instances in which the Program failed to take appropriate action when potential concerns were identified with the prescription and utilization of monitored drugs. Additionally, a methadone program was accidentally excluded from monitoring reports for 21 months.

- 5.42 Reports Drug utilization review intervention reports are generated every 56 days to identify those individuals who received a medication dosage in excess of an established threshold. Reports are reviewed to identify instances which may suggest inappropriate prescribing, abuse or misuse. For situations identified as requiring follow-up, an automated letter is sent to the prescriber requesting an explanation for the medication and dosage prescribed. Responses are assessed for reasonableness. If uncertainty exists regarding the response, additional information may be requested or the Program's medical consultant may be contacted. If Program staff are satisfied with the prescriber's response, the case is closed with no further action required.
- 5.43 Multiple prescriber reports are generated every 28 days to identify individuals who have received prescriptions from three or more prescribers. If it appears a patient may be trying to inappropriately obtain prescriptions for monitored drugs from more than one prescriber, staff may send letters notifying prescribers of this activity. These letters are sent for information only; prescribers are not required to provide a response to the Program.



- 5.44 *Thresholds* Currently, both drug utilization review and multiple prescriber reports are very large.
  - The drug utilization review reports averaged 2,000 situations identified as exceeding thresholds; only 2% of these cases resulted in letters to prescribers and further analysis.
  - The multiple prescriber reports averaged 215 situations identified, with notification letters sent in 13% of these cases.
  - In many instances, the same individuals are flagged on these reports regardless
    of whether their circumstances have changed. This includes instances in
    which a prescriber has already given the Program a reasonable explanation,
    and instances in which Program staff previously determined a letter was not
    necessary.
- 5.45 One person is responsible for the review of both drug utilization and multiple prescriber reports. We were told this review takes approximately three days to complete. With an average of 2,000 situations identified on each drug utilization report, most cases can only receive a very brief review. Furthermore, the size of the reports greatly increases the risk of human error. We are concerned whether a thorough and consistent review of each case can be completed. We found a drug category was mistakenly excluded from the drug utilization review for three consecutive reports during our audit period. The previous seven drug utilization review reports flagged approximately 2,100 cases. This dropped to roughly 1,300 for three reports, a decline of 40%. While these errors were eventually detected by Program staff, the exclusion of a drug category, and resulting 40% decline in the size of the reports, should have been detected immediately. The fact that this went unnoticed for three reports further highlights the challenges with manually reviewing large reports.
- 5.46 Program staff's review of the drug utilization report is a key monitoring activity used to identify trends to guide education and promotion of appropriate use, and trends indicating possible instances of inappropriate prescribing and potential abuse or misuse of monitored drugs. The reports are generated based on a single variable comparing the prescribed medication dosage to the Program's threshold for each drug category. Program staff told us that there are other factors which are considered as reports are reviewed in determining whether follow-up is necessary. Similarly, multiple prescriber reports are generated based on the number of prescriptions the individual has received during the report period, but the manual review of these reports considers several other factors.
- 5.47 Very few letters are issued relative to the number of cases flagged in each report. This suggests that either the thresholds are flagging many acceptable prescriptions, or the review process is failing to identify many problem cases. The Program needs to better utilize technology to target several variables representing the more significant risks and ensure the majority of cases flagged require further follow-up. This would reduce the likelihood of human error associated with manually reviewing large



- volumes of data as well as make better use of limited Program resources than the current intensive manual review process.
- 5.48 We also found report thresholds are not reviewed on a regular basis. Program staff told us that the drug utilization review report thresholds are currently under review, although there is no timeline for completion. This review of thresholds should be conducted in conjunction with establishing additional variables for reports as discussed above and should be linked to best practices where possible.

The Nova Scotia Prescription Monitoring Program should redesign its drug utilization review and multiple prescriber reports to better use technology and reduce the reliance on manual review. The Program should aim to develop reports in which the majority of items flagged require further follow-up.

# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The Department will direct the Board to undertake a complete revision of the Program's drug utilization review process. The Board's Drug Utilization Review Committee, along with the epidemiological expertise of the newest Departmental representative on the Board, can assist the Administrator in building a new drug utilization review framework based on internationally established evidence and validated indicators. The review is expected to be complete in 2013 with implementation in 2014. The Department will monitor progress toward completion of this initiative.

#### Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation and will direct the Administrator to, as part of its quality assurance activities and with the assistance of experts, undertake a comprehensive review of its drug utilization review process in 2013 and implement the resulting updated review framework/process in 2014.

- 5.49 Concerns with report review process Although the Prescription Monitoring Program has established criteria to review drug utilization and multiple prescriber reports and identify items for follow-up, we found the criteria are poorly defined. Additionally, staff reviews of these reports are not linked to criteria. Although it is clear that Program staff review drug utilization and multiple prescriber reports, there is no support for how they determine which cases should be followed up, and no evidence to document the review. The only evidence is a notation in the Program database for those cases in which a letter was sent.
- 5.50 Lack of consistency We analyzed the data from the drug utilization reports during our audit period and found there was no consistent pattern to the situations for which letters were sent. We identified many instances in which a letter was sent when someone was one to two percent over the threshold; conversely, there were also many instances in which letters were not sent when an individual was prescribed 10 to



20 times the dosage threshold. While Program staff were able to provide possible explanations, there was no documentation to confirm this was the rationale considered when the cases were reviewed. Given these inconsistencies and the absence of any documentation supporting why cases were identified for follow-up, it is impossible to know whether all situations were followed up or whether the action taken was appropriate.

- 5.51 *Testing* We reviewed the 17 drug utilization reports and 34 multiple prescriber reports prepared during our audit period and selected samples from each to determine whether decisions reached were supported.
- 5.52 We were unable to determine why cases were identified for further follow-up or why other situations were deemed acceptable. Since there is no documentation of the review, staff were only able to provide potential reasons for actions taken. Additionally, one of the items we identified for testing had been reviewed by a staff member who is no longer with the Program. The current staff member responsible for reviewing these reports felt a letter should have been sent, but because there is no documentation, was unable to explain why this situation was not followed up. Adequate documentation of the review, along with the reason for final decisions, is necessary to ensure all cases receive an appropriate review and are treated consistently.
- 5.53 We also found there is no independent review of staff's assessment of drug utilization and multiple prescriber reports.

#### Recommendation 5.9

The Nova Scotia Prescription Monitoring Program should document support for all decisions made during the review of the drug utilization review and multiple prescriber reports, including decisions regarding whether to follow-up and whether responses are acceptable.

#### Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The Department will direct the Board to undertake a complete revision of the Program's drug utilization review process. The Board's Drug Utilization Review Committee, along with the epidemiological expertise of the newest Departmental representative on the Board, can assist the Administrator in building a new drug utilization review framework based on internationally established evidence and validated indicators. The review is expected to be complete in 2013 with implementation in 2014. The Department will monitor progress toward completion of this initiative.

## Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation and will direct the Administrator to include documentation policies and mechanisms that will support all decisions made during the drug utilization review process as part of the updated drug utilization review framework/process noted in the response to Recommendation #8, with an implementation date of 2014.



The Nova Scotia Prescription Monitoring Program should implement a quality assurance process to review the adequacy and appropriateness of the work completed by staff on the drug utilization review and multiple prescriber reports as well as other Program reports.

# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The Department will direct the Board to undertake a complete revision of the Program's drug utilization review process. The Board's Drug Utilization Review Committee, along with the epidemiological expertise of the newest Departmental representative on the Board, can assist the Administrator in building a new drug utilization review framework based on internationally established evidence and validated indicators. The review is expected to be complete in 2013 with implementation in 2014. The Department will monitor progress toward completion of this initiative.

#### Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation. As with Recommendation #9, the Board will direct the Administrator to include, as part of the updated drug utilization review framework/process noted in the response to Recommendation #8, a quality assurance process to review the adequacy and appropriateness of the work completed by staff on the drug utilization review process, with implementation in 2014.

- 5.54 Enforcement processes The Program may send letters to prescribers following the review of a drug utilization report. Prescribers are required to provide a response. The Program's medical consultant may also contact prescribers to discuss the specifics of a situation or may request additional information. If the prescriber does not reply before the deadline, a second letter is sent. If a response is still not provided, a final letter is sent indicating the matter will be referred to the College of Physicians and Surgeons of Nova Scotia if a reply is not received.
- 5.55 We tested 24 initial letters to prescribers and identified three instances in which the file was closed even though the prescriber failed to respond to letters from the Program. While additional evidence may dictate a case can be closed, it is important the Program require all prescribers to respond to its requests for information. The Program should also document decisions made in these cases.
- 5.56 We also found three situations in which a final letter was not sent in a timely manner.
  - Two letters were sent between 19 and 22 days after the deadline in the second letter had passed.
  - In one instance, the Program received a response 19 days after the deadline provided on the second letter. A third letter had not been sent, although one should have been triggered as soon as the deadline in the second letter expired.



- 5.57 If prescribers do not respond to the final letter from the Program there is the option of referring the matter to the College of Physicians and Surgeons of Nova Scotia. However, flexibility is needed to account for situations in which prescribers are not able to provide a response by the established deadline for legitimate reasons.
- 5.58 Timeliness of medical consultant review The sample we selected from drug utilization review reports included three cases which were referred to the medical consultant for review. While all three situations were reviewed, there is no evidence of when the review was actually completed. The review results were entered in the Program's system between 44 and 92 days after the initial referral to the medical consultant. The contract with the medical consultant establishes review timeframes of between seven and 30 days, although Program management told us these deadlines are not used in practice. Timely review by the medical consultant is important to address potentially inappropriate prescribing practices and prevent misuse or abuse of monitored drugs from continuing for longer than necessary.

The Nova Scotia Prescription Monitoring Program should implement standard timeframes within which cases referred to the medical consultant should be reviewed. Referrals should be monitored to verify these timeframes are met.

# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The Department will direct the Board to develop a policy that identifies standard timeframes, based on criticality of cases, within which cases referred to the medical consultant should be reviewed. The policy will be complete in 2013 and implemented as soon after as possible. The Department will follow up with the Board in 2013 to ensure compliance.

#### Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation and will direct the Administrator to develop, for Board approval, a policy outlining expected review timelines for cases forwarded to the Program's medical consultant. This policy will be based upon the appropriate prioritization of the cases in recognition of the part-time status of the medical consultant. The policy will be developed and implemented in 2013.

- 5.59 Complaints The Program receives complaints regarding potential abuse or misuse of monitored drugs from a variety of sources including the public, pharmacists, physicians and law enforcement. We reviewed a sample of 21 complaints and found all were addressed in accordance with Program policies. However, we were unable to determine if seven of these complaints were addressed in a timely manner as the completion date was not documented. The remaining 14 complaints were dealt with in a timely manner.
- 5.60 *Practice Review Committee* Fourteen prescribers were referred to the Practice Review Committee during our audit period. This Committee provides peer review



of prescriber responses to the Program. We found the Committee took timely and appropriate action in all cases. The Practice Review Committee subsequently referred three of these prescribers to the College of Physicians and Surgeons of Nova Scotia. We note the Program found that the prescribing practices of each decreased subsequent to the referral to the College, suggesting this was a deterrent to inappropriate prescribing

5.61 *Monitoring of methadone programs* – Methadone patients cannot take most other monitored drugs for safety reasons. The Program uses weekly reports to identify any patients in publicly-funded methadone programs who have received monitored drugs, other than methadone. The reports do not identify methadone prescriptions. This is a gap in the Program since a patient could obtain additional methadone from another prescriber and this would not be detected by these weekly reports.

#### Recommendation 5.12

The Nova Scotia Prescription Monitoring Program's reviews of publicly-funded methadone treatment should identify all prescriptions for monitored drugs, including methadone.

# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The Department will direct the Board to require the Administrator to include methadone in its regular review of publicly-funded methadone treatment programs by the end of 2012. The Department will follow up with the Board in early 2013 to ensure compliance.

#### Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation and will direct the Administrator to undertake the changes needed to include all monitored drugs in its review of publicly-funded methadone treatment by the end of 2012.

5.62 We also found that weekly reports were not run for 21 months for the clients of one publicly-funded methadone program. The program name was entered into the information system incorrectly. Instead of providing an error message that the program name was not found, the system returned a message that there were no prescriptions of other monitored drugs for these clients.

#### Recommendation 5.13

The Nova Scotia Prescription Monitoring Program should change the error messages that occur when a program name entered to generate a report is not found to clearly state that fact, rather than simply returning no data.

#### Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The Department will direct the Board to require the Administrator to address the system rule that currently returns no data, rather than an error message, when a program name



entered to generate a report is not found. The Department will follow up with the Board to ensure the system rule is addressed by 2013.

# Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation and will direct the Administrator to take the necessary steps by the end of 2012 to ensure that when a program name entered to generate a report is not found, the error message will clearly state that fact.

- 5.63 *Physician-patient agreements* In certain situations, physicians may require patients with monitored drug prescriptions to sign an agreement stating they will only receive monitored drugs from that prescriber. The Program maintains a record of these agreements and runs weekly reports on these patients. The reports are reviewed to identify monitored drugs which were prescribed by physicians not covered by the agreement and a letter is sent to the prescriber.
- 5.64 Both the methadone and patient agreement reports require Program staff to manually review the reports and identify inappropriate prescriptions. If the Program's automated reports were tailored to only identify the problem prescriptions, this manual review would not be necessary. This would reduce the workload of Program staff, as well as eliminate the possibility of human error in reviewing these reports each week.
- 5.65 We selected a sample of 30 weekly methadone monitoring reports and 30 patient agreement reports. We tested one patient from each report whom we had identified as either having received monitored drugs while taking methadone, or as receiving drugs from another physician after agreeing not to. We found the Program failed to take appropriate action in six of the 60 cases we reviewed; in these instances the prescribers were not informed that their patients had received monitored drugs from another prescriber or pharmacist. Program staff need to ensure letters are sent when required. Recommendation 5.10 in this Chapter notes the need for a quality assurance process to check staff work; implementing this recommendation will also help address this issue.

# Recommendation 5.14

The Nova Scotia Prescription Monitoring Program should comply with their policy and send notification letters to all prescribers when instances of patient noncompliance are identified.

#### Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The Department will direct the Board to require the Administrator to comply with the policy immediately. The Department will follow up with the Board before the end of 2012 to ensure compliance.

#### Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation and will direct the Administrator to take the necessary quality assurance steps to ensure continued compliance with its policy. The



steps will include a new method for documenting the activities, which will more clearly demonstrate compliance with the policy. This will be implemented by the end of 2012.

# **Duplicate Prescription Pads**

#### Conclusions and summary of observations

Prescriptions for monitored drugs must be written on duplicate prescription pads that are only available through the Program. We identified issues with the manner in which prescription numbers could be assigned, but overall, found the security over issuing and storage was adequate. There are policies and procedures in place related to voiding lost, stolen or forged prescriptions, as well as unused prescriptions when a prescriber leaves the Program. However, we found these policies are not always followed. We identified several instances in which prescriptions or pads reported as stolen or forged were not identified as void in the system or were not voided in a timely manner. Furthermore, unused prescriptions of prescribers who left the Program were also either not voided or not voided promptly.

- 5.66 Issuing duplicate prescription pads Prescriptions for monitored drugs must be written on duplicate prescription pads, which are only issued to prescribers registered with the Program. When prescribers order duplicate prescription pads these are printed the following day and sent via courier. The inventory of templates and assembled pads are kept in a secure room which can only be accessed by a limited number of Medavie (the Program's contracted administrator) employees. A small inventory of blank prescription pads is also kept in another secure location that only Program staff can access.
- 5.67 In certain situations, internal prescription pad numbers are generated in the system, effectively creating a prescription number without a corresponding physical prescription. The main reason for this occurs when a pharmacy contacts the Program because prescriptions for two monitored drugs were written on one prescription form. Prescription Monitoring Regulations only allow one monitored drug per prescription. The Program generates a prescription number so the pharmacist can have a valid number for each prescription. However, staff do not confirm with the original prescriber that both prescriptions are valid unless this becomes a regular occurrence.
- 5.68 The Program has policies for issuing and tracking duplicate prescription pads. We tested a sample of 40 prescribers who prescribed monitored drugs during our audit period and found all were registered with the Program when the prescriptions were issued.
- 5.69 *Voiding duplicate prescription pads* When duplicate prescription pads are reported lost, stolen or forged, an alert may be sent to pharmacies and the individual prescription numbers are flagged as void in the online system. If a prescription number from a void pad is entered in the online system, the pharmacist receives



- a response code notification. However, as discussed earlier, pharmacists can use professional judgement to determine whether to ignore notifications and continue to dispense the medication.
- 5.70 During our audit period, there were 15 alerts issued for stolen prescription pads containing 225 individual blank prescriptions. Five of these blank prescriptions were not voided and remained active at the time of our audit. Another alert for 23 forged prescriptions included one prescription which was not voided until 11 days after the alert was issued. The remainder were either marked filled, voided, inactive, or stolen prior to or at the time the alert was issued. Failure to promptly cancel known stolen and forged prescriptions means those prescriptions could be used to obtain monitored drugs illegally.

The Nova Scotia Prescription Monitoring Program should establish a process to ensure all prescription pads reported as lost, stolen or forged are cancelled immediately.

# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. The Department will direct the Board to require the Administrator to develop a process to ensure all prescription pads reported as lost, stolen or forged are cancelled immediately. The Department will follow up with the Board to ensure this process is in place by the end of 2012.

#### Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation and notes that this process is already in place. The Board will direct the Administrator to develop and implement a quality assurance process to ensure ongoing compliance with this process by the end of 2012.

- 5.71 When prescribers retire or leave the Program they are supposed to shred unused duplicate prescription pads. When the Program is notified that a prescriber is leaving, any unused prescription pads issued to that prescriber are to be voided by the Program to prevent improper use. We tested 30 prescribers who left the Program during our audit period and identified 13 with a total of 930 prescriptions which were not voided. Another six prescribers unused prescription pads remained valid until between 11 and 143 days after notification of the prescriber leaving the Program. Since prescribers are not required to return unused prescription pads, canceling these prescription numbers in a timely manner is very important. If these prescription pads are not destroyed by the prescriber, they could be lost or stolen and used to obtain monitored drugs illegally.
- 5.72 We also found prescribers are not removed from the list of registered prescribers until one year after they give notice of intent to leave the Program. Additionally, these prescribers are allowed to obtain new duplicate pads, although any numbers issued to them are supposed to be automatically marked as void in the system. It is



not clear why the Program would issue duplicate pads and immediately mark them as void. If a prescriber leaves the Program, the individual should be removed from the list of registered prescribers immediately. If notice is given of intent to leave at some future date, prescriptions should remain valid up to that time. Automatically voiding new pads issued means someone who has notified the Program of plans to retire in one month will have current prescriptions marked as void. Depending on the pharmacist dispensing the medication, this may mean patients are not able to fill valid prescriptions for monitored drugs.

#### Recommendation 5.16

The Nova Scotia Prescription Monitoring Program should not issue duplicate prescription pads to prescribers who are leaving the Program unless these prescribers can demonstrate the need for additional duplicate pads during their remaining time with the Program.

#### Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation. When the DIS assumes the prescription capture functions for the Program, the prescription pads will be eliminated. In the meantime, the Department will direct the Board to require the Administrator to confirm processes to address the issue of duplicate prescription pads are implemented by the end of 2012. The Department will follow up with the Board in early 2013 to ensure compliance until the DIS assumes this function.

# Nova Scotia Prescription Monitoring Board Response:

The Board agrees with this recommendation and notes that it is current practice. The Board will direct the Administrator to develop and implement a quality assurance process to ensure ongoing compliance with this practice by the end of 2012.

5.73 We recognize that while many of the recommendations made in this Chapter can be easily implemented, others will require support and commitment from all parties involved, including the Department of Health and Wellness, to ensure implementation.

#### Recommendation 5.17

The Nova Scotia Prescription Monitoring Program, Board, and the Department of Health and Wellness should work together to determine the most efficient and cost-effective means of applying the recommendations in this Chapter.

# Department of Health and Wellness Response:

The Department of Health and Wellness agrees with this recommendation and will immediately begin working with the Board to determine the most efficient and cost-effective means of applying the recommendations of this Chapter. The goal is to have acted on all responses by the end of 2014.

#### Nova Scotia Prescription Monitoring Program Board Response:

The Board agrees with this recommendation and commits to collaborating with the DHW



to determine the most efficient and cost-effective means of applying the recommendations of this Chapter and to act upon the DHW and Board responses by the end of 2014.



# Department of Health and Wellness Additional Comments

The Department of Health and Wellness notes the audit recognizes the dual mandate of the Prescription Monitoring Program (encouraging appropriate use and monitoring abuse), but is not in agreement with the Auditor General's assessment that the Program emphasizes its education mandate over its monitoring mandate. The audit scope was not sufficient to make this determination as, "we [the Auditor General] focused our audit largely on the monitoring type activities the Board conducts, as these provided some coverage of all aspects of its mandate."

The Department appreciates the thorough review by the Auditor General on the Prescription Monitoring Program. The Department agrees with all of the recommendations pertaining to the Department and recognizes the importance of monitoring the prescribing and utilization of monitored drugs and appropriate action when potential abuse is identified. Over the next year, the Department will direct the Board on developing and enhancing existing measures for monitoring and evaluating the Board's related compliance.



#### Office of the Auditor General Comments

The Board has provided additional comments in their response to this Chapter which can be found below.

It is not our practice to attempt to compare Nova Scotia programs with those of other provinces. We are not in a position to verify information available publicly on the internet or elsewhere regarding these programs.

The use of outside expertise was not necessary for this audit.

#### Nova Scotia Prescription Monitoring Board Additional Comments

The Board has confidence in the Program's performance and effectiveness with respect to its legislated mandate to promote the appropriate use of monitored drugs and the reduction of the abuse/misuse of monitored drugs. It recognizes the importance of continuous quality improvement and will collaborate with the DHW to incorporate the recommendations of the Auditor General into the Program's ongoing quality assurance processes.

While the Board agrees with the individual recommendations, it is disappointed with the overall tone of the report and is of the position that it would have benefitted from the report providing comment on whether or not the Program is meeting its mandate. The opportunity existed for the report to acknowledge the existence of a valuable and unique entity of which Nova Scotians should be proud. If that had been the case, the recommendations concerning the need for ongoing Program enhancements and the identification of additional resources to support valuable initiatives would have been a more positive investment in the Program's objectives and its future.

The Board is of the opinion that the audit would have been of even more value to the Board, the Program Administrator and the Nova Scotia public if the Program's performance had been benchmarked against other prescription monitoring programs across the country or industry best practices and further, if the expertise of clinical experts had been utilized during the audit process.

The Board does not agree with the report's suggestion that the Board appears to emphasize education over active monitoring. The Board agrees that its work in the area of education is critical to achieving the Program's legislated mandate of promoting the appropriate use of monitored drugs and the reduction of the abuse/misuse of monitored drugs; however these efforts are not being carried out in a manner that is disproportionate or detrimental to its monitoring role.