

## Chapter 3

### Section 3.10

# Long-term-care Homes— Medication Management

## Background

Long-term-care homes in Ontario provide care, services, and accommodations to individuals unable to live independently and requiring the availability of 24-hour nursing care and supervision in a secure setting. There are more than 600 such homes in Ontario caring for about 75,000 residents, most of whom are 65 or older. All homes fall within one of four categories: for-profit and not-for-profit nursing homes, charitable homes, and municipal homes for the aged, as illustrated in Figure 1.

Under the *Long-Term Care Act*, the Ministry of Health and Long-Term Care (Ministry) funds long-term-care homes for residents who meet its eligibility requirements for care. Starting April 1, 2007, Ontario's 14 Local Health Integration Networks also began playing a role in the planning and funding of long-term-care homes. In the 2006/07 fiscal year, funding to long-term-care homes for eligible residents totalled \$2.8 billion. The amount paid by the Ministry covers only a portion of the total costs, and therefore long-term-care-home residents with sufficient resources also pay between \$1,500 and \$2,100 a month for their accommodations, depending on whether they occupy a basic, semi-private, or private room. As well, residents make a

**Figure 1: Ontario's Long-term-care Homes by Type, December 2006**

Source of data: Ministry of Health and Long-Term Care

Home Type	# of Homes	# of Beds
nursing home (for profit)	352	39,862
nursing home (not-for-profit)	100	11,664
charitable (not-for-profit)	59	6,982
municipal (not-for-profit)	103	16,620
<b>Total</b>	<b>614</b>	<b>75,128</b>

co-payment to the pharmacy contracted by the home for their drug costs (normally \$2 per prescription), and they are responsible for paying the full cost of most drugs not covered by ministry programs.

Long-term-care homes are licensed or approved by the Ministry under three different laws: the *Nursing Homes Act*, the *Charitable Institutions Act*, and the *Homes for the Aged and Rest Homes Act*. The three Acts do not have identical requirements, but the same ministry policies (set out in the *Long-Term Care Homes Program Manual*) apply to all long-term-care homes.

Under these three Acts, the Ministry is responsible for setting standards of care and conducting inspections of homes. These include complaint investigations and annual unannounced inspections to monitor compliance with legislation, regulations, standards and criteria, and service

agreements. Inspections are intended to safeguard residents' rights, safety, security, quality of care, and quality of life. Where necessary, the Ministry uses its enforcement powers to achieve compliance. However, physicians, contracted pharmacies, and nurses working at the homes all have professional responsibilities for medication management, as shown in Figure 2.

The *Nursing Homes Act*, the *Charitable Institutions Act*, the *Homes for the Aged and Rest Homes Act*, and the *Long-Term Care Act* were in force at the time of our audit, but they will all be replaced by Bill 140, *An Act Respecting Long-Term Care Homes*, which received royal assent in June 2007. The new legislation is expected to provide more consistency among long-term-care homes.

In the 2006/07 fiscal year, the Ministry's Ontario Drug Benefit Program paid pharmacies about \$333 million for more than 19 million drug prescriptions and associated dispensing fees for residents of long-term-care homes. The \$333 million comprises \$203 million for drugs (on average, about \$2,700 per resident) and \$130 million in dispensing fees (about \$1,700 per resident). As well, the Ministry's Ontario Government Pharmaceutical and Medical Supply Service provides certain drugs, such as acetaminophen (generic Tylenol), at no charge to long-term-care homes. In 2006/07, the cost of such drugs was about \$3.4 million.

There are a number of legislative, regulatory, and ministry directives regarding the administration of drugs to residents of long-term-care homes. Given the importance of appropriate medication management at the homes, our audit focused on a review of these practices.

## Audit Objective and Scope

This constitutes the first value-for-money audit in the long-term-care home sector following an expansion of the mandate of the Office of the Auditor General of Ontario in 2005. This expansion allows us to conduct value-for-money audits of institutions in the broader public sector, including hospitals and long-term-care homes. We began performing broader-public-sector audits in the 2005/06 fiscal year.

The objective of our audit was to assess whether medications for residents of long-term-care homes were managed in an efficient, safe, and appropriately controlled way, in accordance with applicable legislation and required policies and procedures (we note that such medication management involves physicians and pharmacists, as well as the homes). We also performed some system-wide work on drugs dispensed to residents of long-term-care homes. However, since medications are prescribed by physicians, we did not attempt to assess

### Figure 2: Medication Management—Professional Responsibilities

Source of data: Ministry of Health and Long-Term Care

**Physicians:** Prescribe medications for long-term-care home residents and review the resident's care plan—including medications—on the basis of the physician's knowledge and skill and the clinical situation of an individual resident. Physicians are accountable to their regulatory body, the College of Physicians and Surgeons of Ontario.

**Pharmacists:** Dispense medications for long-term-care home residents on the basis of physicians' or other recognized health professionals' prescriptions and the pharmacist's knowledge of the resident and the prescribed drug, in accordance with provincial and federal legislation as well as in accordance with the standards of practice of their regulatory body, the Ontario College of Pharmacists.

**Nurses:** Apply their knowledge of the resident and the medication when assessing residents, administering medications, evaluating residents' reaction to medications, and planning and documenting the medication administration process, as per the Medication Practice Standard of the College of Nurses of Ontario. Nurses act as the liaison between the physician and pharmacist in relation to medication management for each resident, and collaborate with the health-care team in the long-term-care home to maintain safe medication-management processes.

the appropriateness of medications prescribed for any individual resident at the homes we visited.

Our audit work was conducted primarily at three long-term-care homes of different types and sizes providing services to a variety of communities: Hamilton Continuing Care, a 64-bed for-profit nursing home; Leisureworld St. George, a 238-bed for-profit nursing home in Toronto; and Providence Manor, a 243-bed charitable home in Kingston. The audit work we conducted at the homes excluded municipally run long-term-care homes because the *Auditor General Act* does not apply to grants to municipalities (other than requiring the Auditor General to examine a municipality's accounting records to determine whether a grant was spent for the purposes intended).

In conducting our audit, we reviewed relevant files and administrative policies and procedures, and met with appropriate staff of long-term-care homes and the Ministry. As well, we obtained and analyzed information on drugs dispensed to residents of all long-term-care homes through the Ministry's Ontario Drug Benefit Program. We also met with the Ontario Long-Term Care Association and the Ontario Association of Non-Profit Homes and Services for Seniors, which between them represent the majority of long-term-care homes in Ontario. In addition, we met with other organizations, including the Ontario College of Pharmacists, and with the staff of a municipal home to familiarize ourselves with issues relating to medication management in long-term-care homes. We also examined the Ministry's inspection and other reports as they related to medication management at the homes we visited, and we reviewed relevant literature, including publications by the Institute for Clinical Evaluative Sciences and the Institute for Safe Medication Practices Canada, as well as information from other jurisdictions. In addition, we engaged on an advisory basis the services of two independent consultants who have expert knowledge of medication management in long-term-care homes.

Our audit was conducted in accordance with the standards for assurance engagements, encompassing value for money and compliance, established by the Canadian Institute of Chartered Accountants, and accordingly we included such tests and other procedures as we considered necessary in the circumstances. The criteria used to conclude on our audit objective were discussed with and agreed to by senior long-term-care home management.

We did not rely on the Ministry's internal audit service team to reduce the extent of our audit work because it had not recently conducted any audit work on medication management in long-term-care homes. None of the homes we visited had an internal audit function, although, in some cases, a home's pharmacy conducted certain compliance procedures, which we reviewed and relied on where warranted. As well, staff at two of the homes conducted certain procedures—which we reviewed—to help verify that medications were properly administered.

## Summary

All three of the long-term-care homes we visited had procedures in place to ensure that they obtained physician-prescribed medications and administered them to residents in a safe and timely manner. However, we noted ways in which homes could improve their medication-management practices—for example, by ensuring that informed consent is obtained from residents or their substitute decision-makers for the use of new medications, monitoring high-risk residents more closely than other residents for adverse drug reactions, documenting such monitoring, and ensuring that expired medications are properly identified and disposed of. In addition, further efforts were needed to promote the secure storage and handling of drugs,

particularly those most susceptible to misappropriation. Some of our more significant observations included the following:

- Two of the three homes we visited generally had no documentation to show they had obtained the informed consent required to treat a resident with new medication. Documentation at the third home generally indicated that consent had been sought—but it did not include the identity of the person contacted.
- The Institute for Safe Medication Practices Canada indicates that the identification and review of medication errors is important to assist in preventing similar errors in the future. However, there is no standard definition for long-term-care homes of a medication error. As well, through our review of various records, we confirmed that there were unreported medication errors at all the homes we visited. In fact, two of the homes were especially poor at ensuring that all medication errors were reported. During 2006, one reported only 12 errors and the other only 26, while the third home took this issue more seriously and reported many more errors.
- International experts have concluded that certain medications are generally more harmful than beneficial to older adults, although there may be the occasional situation where experienced health-care professionals determine that these drugs are the best choice. However, we noted that, during the 2006 calendar year, more than 5,700 residents 65 and over in long-term-care homes across Ontario were prescribed and dispensed at least one of the eight high-risk drugs in our sample. In addition, these drugs were dispensed to at least 20% of residents in 30 Ontario homes. As well, one antibiotic was dispensed to 675 residents in 2006 despite the existence of studies indicating the drug should rarely or never be used in the elderly because it is generally ineffective and has potential adverse side effects. One-fifth of all the residents who received this antibiotic lived in just 12 homes. While we acknowledge that there may be situations where the use of these drugs is warranted, given the higher level of usage we detected in certain homes, this is an area where follow-up by the Ministry of Health and Long-Term Care, in collaboration with the College of Physicians and Surgeons of Ontario, should be considered.
- At the three homes we visited, between 23% and 28% of residents (at least 65 years of age) were taking 12 or more different regularly scheduled medications. While we acknowledge that residents of homes often require various medications because they suffer from a number of conditions, studies have established that the likelihood of an adverse drug event increases with the number of medications taken by an individual. While the homes indicated they monitored all residents, none had any specific policies or procedures for increased monitoring of individuals taking this many medications.
- In 2006, there were 18,000 level-1 alerts, generated automatically by computers at pharmacies to warn that a drug combination is clearly contra-indicated and should not be dispensed or administered. These alerts are updated monthly on the Ministry's Ontario Drug Benefit Program system, on the basis of the results of research provided by a third-party organization specializing in medication management. We noted that 91% of these alerts were overridden by the pharmacist and the drugs dispensed to residents of 421 long-term-care homes. While pharmacists may have contacted the prescribing physician to discuss these drug interactions, we believe Ministry monitoring and follow-up, in collaboration with the College of Physicians and Surgeons of

Ontario, may be warranted given such a high percentage of overridden alerts.

- None of the homes we visited performed periodic reconciliations of controlled substances administered to residents with records of drugs received from the pharmacy and those on hand. We reconciled a sample and found discrepancies at all the homes.
- Processes were not in place to ensure that expired medication was always identified and removed from the supply of drugs awaiting use. We found that almost 30% of the drugs in the emergency supply at one home had expired—one medication was 10 months out of date. At another home, some medications ordered in bulk were more than a year past their printed expiry date.
- None of the homes consistently monitored the quantity of the free drugs they received from the Ontario Government Pharmaceutical and Medical Supply Service that expired prior to use; doing so would facilitate better inventory management and reduce waste.
- Two of the homes were not consistently using environmentally responsible practices to dispose of medications. For example, we were informed that some unused injectable narcotics were poured down the drain, and spoiled pills were thrown into the garbage.

We sent this report to the three long-term-care homes we visited as part of this audit, and to the Ministry of Health and Long-Term Care, and invited them to provide a response. We received responses from each of the three long-term-care homes and from the Ministry. To be succinct and avoid repetition, we summarized the overall response we received from the long-term-care homes below, followed by the Ministry's overall response. Responses by the long-term-care homes and the Ministry, where applicable, to specific recommendations are summarized following each recommendation.

## SUMMARY OF LONG-TERM-CARE HOMES' OVERALL RESPONSE

Overall, the homes generally agreed with our recommendations and provided detailed responses to individual recommendations.

## OVERALL MINISTRY RESPONSE

Some of the recommendations directed to the Ministry are within the scope of professional practice of physicians, pharmacists, or nurses. The College of Physicians and Surgeons of Ontario, the Ontario College of Pharmacists, and the College of Nurses of Ontario are responsible for setting practice standards and maintaining a regulatory process for their members. Each has processes to evaluate the quality of practice in order to improve patient care. These professional standards are in addition to requirements that exist in legislation.

The Ministry has, in consultation with our partners, including long-term-care homes and their associations, regulatory colleges, and Local Health Integration Networks, developed and implemented some initiatives to improve care and assist long-term-care homes in tracking and reporting as further described in the Ministry's responses to specific recommendations.

The Auditor General's observations on drug-alert overrides and medications that may be contra-indicated for seniors reflect on the prescribing practices of physicians. In the absence of discussions with the College of Physicians and Surgeons of Ontario on these issues, or any specific information regarding the seniors to whom these medications were prescribed, it is difficult to assess the risk, if any, to these residents. However, the Ministry is committed to working with the Ontario College of Pharmacists, the College of Nurses of Ontario, and the College of Physicians and Surgeons of Ontario, as well as

long-term-care homes, on issues that may affect the health of residents in keeping with each partner's responsibilities.

## Detailed Audit Observations

### PROVISION OF MEDICATIONS

Residents of long-term-care homes usually have conditions requiring treatment with medication prescribed by a doctor. Homes contract with pharmacies to obtain prescription drugs for their residents. In addition, homes can order certain over-the-counter drugs free of charge from the Ontario Government Pharmaceutical and Medical Supply Service (Service). In February 2007, the Service began offering free delivery of these medications directly to pharmacies serving long-term-care homes, when requested by the homes, so that the pharmacies could repackage the drugs for individual residents. Since this process was new at the time of our audit, none of the homes we visited had these drugs delivered directly to the pharmacies they contracted with, and therefore we did not audit this process.

Pharmacies can dispense medication in quantities that can be administered to residents for several months at a time. At the homes we visited, however, pharmacies filled most prescriptions with enough medication for only one week, and thereafter refilled the prescriptions weekly. The one-week supply was generally in “strip-packing,” where drugs that are taken together are packaged in pouches marked with the appropriate time and date to take the medication. Pouches are attached together in the order they are to be administered. This process aims to lessen the risk of residents getting incorrect medication or dosages, and to reduce the time nurses spend sorting and administering drugs.

Differences can arise between quantities dispensed by a pharmacy on behalf of a resident and quantities actually administered to that resident for a variety of reasons, including changes to a resident's treatment plan.

### Pharmacies' Monitoring of Homes

Long-term-care homes contract with pharmacies to obtain prescriptions and other medications ordered by physicians for their residents, as well as to obtain advice on such issues as potential drug interactions. The Ministry's *Long-Term Care Homes Program Manual* says there must be a written contract between the home and the pharmacy that includes quality management expectations in areas such as drug storage, prescription and distribution systems, review of resident profiles prior to dispensing of prescriptions, and communication regarding and resolution of any concerns with the physician. The contract may also include requirements for interdisciplinary review, documentation of resident prescriptions, staff education, and drug destruction. According to the Ministry, pharmacy services must be available to long-term-care homes 24 hours a day, seven days a week.

We found that the homes we visited had agreements with pharmacies that complied with ministry requirements and described in general terms the pharmacy's responsibility to monitor potential drug interactions. As well, all homes had an expectation that the pharmacist would perform some procedures to ensure the home's compliance with key medication-related policies, such as the documentation of medication-related processes and the storage of medications. However, none of the agreements with the pharmacies specified the types of procedures that were to be conducted or their frequency, although one home's agreement indicated that the pharmacy was to audit the home regularly, at intervals to be determined. As a consequence, we noted significant variations in the

extent to which pharmacies communicated issues of non-compliance to homes: one home received no such written reports at all in 2006 while another received them in most months of the year.

## Consent to Treatment

Under the *Nursing Homes Act* and the *Charitable Institutions Act*, residents of long-term-care homes have the right to give or refuse consent to treatment with medication in accordance with the law. Under the *Health Care Consent Act*, consent is not required in certain situations, such as emergencies; it also stipulates that providing consent generally requires an understanding of the expected benefits of the medication, significant risks (including side effects), and potential alternative courses of action. People adjudged by a physician or other health practitioner to be mentally incapable of sufficient understanding to make an informed medication-related decision cannot legally give their consent. Many residents of long-term-care homes are incapable of making their own decisions because of chronic illnesses such as Alzheimer's disease. Consequently, a legal substitute decision-maker for these residents, usually a family member and in some cases the Public Guardian and Trustee, must be contacted to give or refuse consent. Given that there may be difficulties in reaching substitute decision-makers, in order to avoid unnecessary delays in treatment it is important that homes have an efficient and timely process to obtain consent.

At the homes we visited, we were informed that few residents were considered capable of making their own decisions about medication. However, none of the homes had a written policy on how to obtain and document consent from a substitute decision-maker, although staff at all the homes indicated that consent should be documented in the resident's file. One home did indicate that it was developing a policy on how to better ensure that consent was obtained and documented for new

psychotropic drugs, which often have a higher risk of adverse reactions.

We were informed that, generally, either the physician or a staff person at the home would attempt to contact a substitute decision-maker about a new medication. In many cases, however, the homes indicated that no consent was obtained because the home could not reach the substitute decision-maker and often was able only to leave a message. We selected a sample of residents who recently started taking new medications and found that two of the homes generally had no documentation of consent from either the resident (if capable) or the substitute decision-maker. Nor were there any indications that these had been emergencies. At the third home, we found documentation to indicate that, in some cases, the home had contacted the substitute decision-maker to discuss a new medication but had not documented that person's name. As well, none of the three homes conducted periodic checks to ensure that consent was documented on the resident's file when required.

## Medical Directives and Standing Orders

The majority of medications are administered on the basis of a physician's prescription, which would normally take into consideration a resident's health history and current condition. One of the homes we visited required that a physician approve all medication administered to a resident. The two others had similar requirements for the majority of drugs but also used a pre-approved list, called "medical directives" at one home and "standing orders" at the other, for five to eight mostly common over-the-counter medications like acetaminophen (generic Tylenol) and dimenhydrinate (generic Gravol). Drugs on this list could be administered in certain circumstances (when a resident experienced pain or nausea, for example) according to a nurse's judgment. The College of Nurses of Ontario's medication practice standard outlines processes that

nurses should follow in administering these drugs. In administering medications, especially when judgment is involved, care should be taken because of the medications' potential side effects. For example, dimenhydrinate commonly causes confusion and falls in older adults, especially those with dementia.

The Ministry requires that homes have policies on standing orders but does not provide further guidance or minimum standards with respect to such orders, nor does the Ontario College of Pharmacists have specific requirements concerning medical directives in long-term-care homes. While the policy of the College of Physicians and Surgeons of Ontario regarding medical directives is also applicable to different settings, it indicates that a medical directive should be signed by the physician and should consist of a number of items, including a detailed list of the specific clinical conditions that the patient must meet and the situational circumstances that must exist before the directive can be implemented, as well as a comprehensive list of contra-indications to implementing the directive. We noted that both the Saskatchewan College of Pharmacists' *Standards of Practice for Pharmacists Providing Services to Long-Term Care Residents* and the College of Pharmacists of British Columbia's *Interpretation Manual for Providers of Pharmacy Services to Residential Care Facilities and Homes* state that standing orders must be personalized to individual residents and signed by the physician. In addition, the British Columbia standard requires that the drugs on each resident's standing order list be reviewed annually by the physician to ensure that they are still appropriate.

As mentioned earlier, two of the homes we visited used medical directives or standing orders, although doctors could exempt a resident from the medical directives or standing orders if, for example, the individual was allergic to a drug. At one home, the policy was that the standing order for each resident was completed by the physician when the resident moved into the home. Subse-

quently, the physician would mark or initial a line, called "routine medical orders signed," on the form used for the quarterly review of the resident's medications or treatments. We were informed that almost all residents were approved for the same list of drugs and that only in rare circumstances was a resident not authorized to receive all standing-order drugs. At the other home, all residents could receive all of the listed drugs in accordance with a medical directive approved annually by the home's medical director. As well, the physician would check a box indicating the approval of "medical directives as needed" on each resident's quarterly review form.

We noted that the Saskatchewan standards stipulate that no standing-order medication is to be given beyond 48 hours without physician approval because symptoms lasting longer than 48 hours may indicate other medical issues requiring a physician's assessment. However, both homes that used standing orders allowed for one common pain medication (acetaminophen) to be administered for 72 hours before a physician was consulted. One home indicated that the reason for the 72-hour duration of the standing orders was to allow for weekend coverage. In light of the potential side effects from the use of over-the-counter drugs and the more detailed guidance provided by some other provinces in this area, the guidance outlined in the Ministry's "standing orders" policy may not be sufficiently detailed.

## Medication Errors

### Identifying and Documenting Medication Errors

The Institute for Safe Medication Practices Canada says full and complete medication-error identification and reporting is important to ensure that residents are not harmed and that actions are taken to ensure that the same errors do not occur in future. As well, the Ministry's *Long-Term Care Homes Program Manual* (Manual) states that after

medication errors are reported, specific follow-up action should be taken. The Ministry's compliance-review monitoring tools for long-term-care homes defines a medication error as any mistake in the administration of medications that requires medical intervention, as well as a pattern of errors. The Manual does not further define these errors, and therefore the definition of an error can vary across homes. The Manual does, however, state that all medication errors should be reported promptly to the home's director of nursing, prescribing physician, and pharmacist according to the home's established policies and procedures. Such policies depend on a clear definition of a medication error in order for staff to recognize and report these errors. The Manual also states that a medication error resulting in an adverse reaction requiring hospitalization should be reported to the Ministry within 10 working days as part of the Ministry's unusual-occurrence reporting requirements. In 2006, 54 such errors were reported by long-term-care homes across the province; no such errors were reported by the three homes we visited.

We found that the policies at one of the homes were not as comprehensive as required by the Manual. For example, this home's policy only required reporting of medication errors that resulted in a resident being hospitalized, or drugs going missing or being misappropriated.

One home we visited had not defined what it considered to be a medication error. The other two homes had defined medication errors as "any incident involving medication administration by nursing or dispensing by pharmacy." Because many policies and procedures for medication systems were not documented, staff were sometimes unclear about what to record as a medication error. At one home, for example, the pharmacist identified potentially missed doses of a drug to treat nausea after chemotherapy, but this was not included as a medication error.

All of the homes we visited required staff to use specific forms to document medication errors. These generally divided medication errors between those that occurred at the home, such as nursing errors, and those that occurred at the pharmacy. One home had a useful form which listed 16 categories of medication-administration errors, including nursing errors, such as incorrect drug and wrong or extra dose, and pharmacy dispensing errors, such as incorrect labelling of medication or wrong medication in packaging.

We reviewed the medication error forms at the homes we visited and found that all homes had reported some medication errors in 2006. One home we visited appeared to take this issue more seriously as it identified more than 150 errors throughout the year. However, the two other homes identified only 12 and 26 errors respectively, with all but three occurring in the first two months of the year at one home. We reviewed other documents available at the homes indicating that medication errors were likely under-reported at the two that reported 12 and 26 errors respectively.

We found that all three homes we visited did not analyze errors by unit or by nurse. Such analysis would help identify potential trends and assist in preventing similar errors in future.

### Medication Errors in Medication-administration Records

At the two homes we visited that defined medication errors, one such error was failure to sign a resident's medication-administration record after a drug is administered. The medication-administration record lists all drugs a resident is to receive and the times at which he or she is to receive them. If the record is not signed, others reviewing the record will not know whether the medication was administered, and the same medication might be administered a second time.

The policy at one home indicated that the best way to ensure timely identification and follow-up

of these types of medication errors was through a daily review of residents' medication-administration records. This home informed us that, as of April 2006, the nurse on duty for night shifts was to review the medication-administration records for that day and highlight any instances of non-compliance so that follow-up could be completed on a timely basis. We obtained the night nurses' review for two months of 2007, as the 2006 records had been destroyed at the end of that year, and found that the medication-administration records had not been reviewed on most days as required by the home's policy. Another home had reviewed the completion of medication-administration records for some but not on most days during eight months in 2006. The third home did not review medication-administration records to ensure that they were signed.

Both homes that reviewed the completion of medication-administration records identified many instances where there was no indication whether medication was administered as required. However, neither of these homes tracked the number of instances where signatures were missing to identify potential trends, a practice which could assist in educating nurses to reduce future occurrences. Missing signatures were sometimes discovered days or weeks later, thereby hindering timely corrective action. We also noted that the follow-up procedures conducted by these homes were sometimes of questionable effectiveness. In some cases, for example, homes contacted nurses one to two weeks after their shift to ask them to sign the medication-administration record to indicate the resident had received the medication.

The homes' and pharmacists' review processes, as well as our review, found instances at all three homes we visited where medication-administration records were not adequately completed. However, only one of the homes included some of these identified cases as medication errors.

## RECOMMENDATION 1

To help promote the safe and efficient provision of medication to residents, long-term-care homes should ensure that:

- contracts with pharmacies specify the type and frequency of procedures the pharmacy is to perform, as well as the reporting methods to be used, with respect to assessing the home's compliance with medication-related policies; and
- consent to treatment with new medication is obtained and documented from either the resident, when capable of giving consent, or from the resident's substitute decision-maker in a timely manner.

The Ministry of Health and Long-Term Care should review its policy on standing orders (which typically relate to over-the-counter medication) to determine if additional guidance is necessary.

As well, to help promote the health of residents, long-term-care homes, in conjunction with the Ministry of Health and Long-Term Care, should develop a consistent definition of what constitutes a medication error. In addition, long-term-care homes should ensure that medication errors are consistently identified, documented, and reviewed so that appropriate action can be taken on a timely basis to minimize similar occurrences in the future.

## SUMMARY OF LONG-TERM-CARE HOMES' RESPONSES

The homes generally agreed with this recommendation. One home highlighted its support for having its pharmacy contract include consistent procedural and written reporting requirements for assessing the home's compliance with medication-related policies, and indicated that it was planning to incorporate these

items into its pharmacy contract. Another home indicated that it would endeavour to incorporate these items into its pharmacy contract.

With respect to consent to treatment, one home pointed out that processes put in place to obtain informed consent must not unreasonably delay the treatment of residents, and noted that obtaining and documenting informed consent from substitute decision-makers is a responsibility shared between the physician, nurse, and pharmacist and is often a complicated process. The home further indicated that it was working with its Pharmacy and Therapeutics Committee to approve a system to document that informed consent has been requested and obtained in an efficient and timely manner. Another home indicated that it was its expectation that the physician, or the nurse in the physician's absence, would obtain consent, but that obtaining substitute consent is not always easy. This home is reviewing its practices for obtaining consent, and expects to implement revised practices by the end of 2007. The third home also indicated that it was implementing a process to ensure that consent is received in a timely manner for new medications.

Two homes highlighted the importance of having a standard definition of a medication error that is consistent throughout the health-care system. One home noted that pending the adoption of such a standard it would work with its contracted pharmacy to clarify further its definition of a medication error. Although this home believed that its policy to track and analyze medication errors was adequate, it planned to provide further training to staff to strengthen this process and would monitor performance. Another home indicated that it was implementing a system to aid in the timely and accurate reporting, tracking, and analysis of medication errors. As this system is

in use elsewhere in Canada, the home expected that the system would provide benchmarking opportunities.

## MINISTRY RESPONSE

The Ministry supports the first part of this recommendation and will work with long-term-care homes and other partners, such as the Local Health Integration Networks, to identify opportunities to better help long-term-care homes meet it.

With respect to Standing Orders, the Ministry notes that their use is within the purview of professional practice, and is not regulated by the Ministry. However, discussions will be undertaken with the appropriate regulatory colleges and stakeholders in the long-term-care-homes sector to ensure that seniors are served well.

Concerning the definition of medication errors, while definitions are included in both the Standards of Practice of the Ontario College of Pharmacists and the Practice Standards of the College of Nurses of Ontario, the Ministry notes that they are not consistent and could contribute to confusion in reporting medication errors in long-term-care homes. To help address this, the Ministry has developed an on-line reporting system that will enable long-term-care homes to meet their unusual-occurrences reporting requirements, including certain types of medication errors, more consistently, and enhance the Ministry's risk-management capacity. Over time, this system can be used to support further clarification and guidance to long-term-care homes on what constitutes a medication error to ensure consistent and accurate reporting. The province-wide rollout of this system was to commence in late 2007.

## REACTIONS TO MEDICATIONS

### Monitoring Residents' Reactions

According to research from various jurisdictions, including Canada and Australia, older adults are more vulnerable than younger adults to adverse drug reactions. These reactions include dry eyes, drowsiness, and hallucinations—and even death. The Ministry's *Long-Term Care Homes Program Manual* (Manual) requires each home to have written policies and procedures for adverse drug reactions, including a system to report them immediately to the home's director of nursing, physician, and pharmacist. Policies help staff identify and document serious adverse reactions, as well as any measures taken to ensure that the reaction does not recur.

At the three homes we visited, contracted pharmacies were responsible for identifying potential adverse drug reactions and interactions before filling the prescriptions. We were informed that computers at the pharmacies contained a medication profile for each resident, listing all drugs prescribed. The medication profile also included medical conditions—diabetes, for example—of which the pharmacist should be aware. After a new medication is prescribed and entered into the profile, the system identifies any potential adverse effects, after which the pharmacist may contact the physician to discuss the situation. The physician may change the medication, or determine that the benefits outweigh the risks, in which case the home is informed of the potential for an adverse effect, and that information may be included in the resident's file. However, homes do not have direct access to the adverse-drug-effects warnings generated by the pharmacy's computer system.

We noted that the professional standards of the College of Nurses of Ontario, which apply to nurses working in long-term-care homes, require them to be aware of current drug information, including contra-indications and potential adverse reactions, as well as to evaluate and document medication

administration and medication-related outcomes. These outcomes include benefits, side effects, and signs of drug interactions. Documenting outcomes is important to ensure that the physician has as much information as possible when making subsequent decisions about prescribing new drugs, changing dosages of existing medications, or discontinuing drugs.

The homes we visited informed us that serious adverse reactions were rare. In addition, they indicated that less severe reactions were also documented in resident files when they occurred. Two homes had a policy that addressed serious adverse reactions, including those relating to newly marketed drugs, and described how they were to be documented in resident files. The documented policies at the other home did not expand on the Ministry's reporting requirements for adverse drug reactions.

None of the homes we visited had a general policy on monitoring and documenting resident reactions to new or changed medications. However, we were informed that residents are monitored daily and that when a change in a resident's condition is observed, it is documented. We were also informed that such monitoring could be documented in as many as five different reports maintained by the home, including progress notes made by nurses in residents' files and multi-resident reports used by nurses to convey key information to the next shift coming on duty.

We reviewed a sample of resident files and other documents at the homes we visited and found that often, there was no documentation of the monitoring of any potential resident reactions to a new drug or a changed dosage. In one case, a resident was prescribed a new psychotropic drug that has a high risk of potential side effects, yet we could find no documented evidence that the resident was monitored for medication-related outcomes in the week that followed the administration of the new drug. Health Canada notes on its website for the Canadian

Adverse Drug Reaction Monitoring Program, which is responsible for the collection and assessment of adverse reaction reports, that adverse reactions remain under-reported.

## High-Risk Medications

### Groups of High-Risk Medications

While there may be occasional situations where these drugs are the best choice, international experts have identified certain medications that are generally more harmful than beneficial to older adults. A well-known analysis of such drugs is the Beers Criteria, which the Ministry indicated are well recognized. In addition, a December 2006 newsletter of the College of Physicians and Surgeons of Ontario noted that the Beers Criteria has become the “most widely used criteria for identifying drugs that potentially increase the likelihood of [adverse drug effects] in elderly patients.” These criteria were developed in 1991 by 12 national experts in the United States headed by a physician, Dr. Mark H. Beers. Subsequently updated in 1997 and 2002, they include approximately 50 medications or classes of medications considered to pose a high risk to adults 65 or older. Most of these are psychotropic drugs, muscle relaxants, and gastrointestinal medications; many are not approved for use in Canada. In 2006, the Washington, D.C.-based National Committee on Quality Assurance (National Committee), a private, non-profit medical organization, convened a consensus panel composed of experts with pharmacological and geriatric-medicine expertise. The National Committee set out to identify which drugs in the 2002 Beers Criteria should *always* be avoided in the elderly. It concluded that 42 drugs were particularly high-risk and were rarely appropriate or should always be avoided. Many of these drugs were not available in Canada. Although the Ministry does not monitor the extent to which any of these medications are dispensed to residents of long-term-care homes, the Ministry’s Health Network System is the

only system that tracks information on most drugs dispensed to all long-term-care-home residents across the province.

At our request, the Ministry compiled a report based on Health Network System data from the Ontario Drug Benefit Program (more details on this system and program can be found in Section 3.05, Drug Programs Activity). This report covered individuals 65 or older who were dispensed at least one of a sample of eight high-risk drugs on the Beers Criteria that are available in Canada, and who also were in a long-term-care home as of January 1, 2006, and remained resident in only that home during the 2006 calendar year. While more than 5,700 long-term-care home residents were dispensed at least one of these medications, the report indicated that 30 homes in Ontario dispensed these drugs to 20% or more of their residents. The three homes we visited were not included in these 30 homes.

From another report prepared for us by the Ministry using data from the Ontario Drug Benefit Program, we found that, in 2006, residents of long-term-care homes in Ontario were not generally dispensed any of a sample of the drugs available in Canada that were identified by the National Committee as being rarely appropriate or always to be avoided in the elderly. We did note, however, that about 675 residents of long-term-care homes were given an antibiotic that the National Committee indicated should rarely be used or always avoided in the elderly because it is generally ineffective and has potential adverse side effects. While this is a small portion of the total number of long-term-care-home residents, we also noted that 20% of these individuals resided in just 12 homes, which included one of the homes we visited.

An April 2007 report in the *Archives of Internal Medicine*, a bimonthly journal of the American Medical Association, reviewed the variation in the use of antipsychotic drugs across 485 long-term-care homes in Ontario. It determined that about

one-third of residents were given a physician-prescribed antipsychotic drug, and that individuals residing in the homes with the highest average prescribing rates were three times as likely to be dispensed an antipsychotic drug as those living in homes with the lowest average prescribing rate, regardless of the residents' clinical indications.

### Psychotropic drugs

Psychotropic drugs are prescribed to address mental health disorders or severe behavioural problems like extreme agitation. This class of drugs has one of the highest rates of potential adverse reactions. While there were no legislative or other ministry requirements with respect to the use of psychotropic drugs at the time of our audit, Bill 140 will, when proclaimed, allow for regulations to be made.

Recognizing that psychotropic drugs can lead to side effects and result in medical and cognitive deterioration, the Ministry used to collect data annually on the rates of use of some of these drugs in long-term-care homes across the province. However, it ceased these collections in 2001 because of concerns over data accuracy.

One of the most common conditions treated with psychotropic drugs is dementia, which is not a specific disease but rather a descriptive term for a collection of symptoms caused by a number of disorders that affect the brain. One in 13 Canadians over the age of 65 has dementia.

Where the benefits of certain drugs outweigh the risks, they may be appropriate for some people with dementia. However, an article in the *Journal of the American Medical Association* in 2005 concluded that most drug therapies, and psychotropic drugs in particular, are not generally effective in managing such symptoms of dementia as agitation and delusions. Although there was evidence of modest effectiveness in one group of psychotropic drugs, this was offset by an increased risk of stroke. The article indicated that interventions that do not require medications should be the first line of treatment

for dementia patients. As well, Canada's *National Guidelines for Seniors' Mental Health*, an evidence-based approach to the assessment and treatment of mental health issues in long-term-care homes, state that psychological and social interventions should generally be used prior to drug therapy.

Since psychotropic drugs have a higher risk of potential adverse effects, the Ministry initiated the *Strategy for Alzheimer Disease and Related Dementias* (Strategy) in 1999 to develop psychogeriatric consulting resources to help diagnose older persons at risk, including those demonstrating aggressive behaviour. The Strategy also sought ways to address the behaviours without first resorting to drugs. However, if drugs were deemed necessary, the Strategy included medication-monitoring forms that indicate possible adverse drug effects, as well as a half-hourly behaviour-monitoring form. These forms could be used after a new psychotropic drug was prescribed, or the dosage on existing medication was changed, to help assess the drug's effects. All of the homes we visited had some familiarity with the Strategy, or with a similar program run by the University Health Network, and all of the homes indicated that they periodically referred residents to one of these programs.

Two of the homes indicated that they used medication-monitoring forms for new or changed-dose psychotropic drugs. One of these homes used the Strategy forms. However, we saw no evidence that the forms were used for the new or changed-dose psychotropic drugs that we reviewed. The other home had developed medication-monitoring forms in response to a ministry compliance inspection recommendation and indicated that it had been using these forms since September 2006 for new or changed doses of psychotropic or pain medications. We reviewed the use of the forms and found that documentation regarding residents' reactions to new or changed-dose psychotropic or pain medications was only partially completed. Also, none of the cases we reviewed had

documented daily monitoring, despite this expectation as set out on the form. Of the files we reviewed where new or changed-dose psychotropic drugs had been prescribed, there were only two instances where a half-hourly behaviour-monitoring form, such as the one developed by the Strategy for monitoring residents, was used.

Two of the homes we visited had no criteria to identify those residents who should be referred to a psychogeriatric program such as the Strategy. Furthermore, although the Ministry indicated that it has provided related training to over 5,000 long-term-care-home staff, we were informed by the homes we visited that only a limited number of nursing staff had psychogeriatric training in accordance with either the Strategy's or the University Health Network's program. Similar concerns about the need for such training were raised by a coroner's jury following a 2005 inquest into the killing of two residents of a Toronto long-term-care home by a third resident.

### Drug Interactions

Residents in long-term-care homes often have a number of medical conditions requiring medication. Various studies have established that the likelihood of an adverse drug reaction increases with the number of medications taken by an individual. A 2005 article in the *American Journal of Medicine* that focused on the incidence of adverse drug events in two large long-term-care facilities, one of them in Ontario, also concluded that a higher number of regularly scheduled medications (which excluded medications taken "as needed") was associated with adverse drug events. Specifically, the study found that residents taking 12 or more regularly scheduled medications were more than twice as likely to experience an adverse event compared to those taking one to five regularly scheduled medications.

The Ministry indicated that system limitations made it impossible to provide us with information on the number of regularly scheduled medications being administered to long-term-care residents at any particular time. However, the pharmacists for the homes we visited provided us with information indicating that between 23% and 28% of residents at least 65 years of age were taking 12 or more regularly scheduled medications in early 2007. None of the homes we visited had specific policies or procedures for monitoring residents who take a large number of medications.

As mentioned earlier, the pharmacy may generate notices about potential adverse drug reactions and drug interactions when a new medication is prescribed for a new resident and may contact the physician to discuss the situation. At our request, the Ministry produced a report on drug interaction notices generated by the Ontario Drug Benefit Program for each long-term-care home. Drug interaction notices are updated monthly, on the basis of the results of research provided by a third-party organization specializing in medication management. The most serious of these notices, called level-1 alerts, indicate a drug combination that is clearly contra-indicated in all cases and should not be dispensed or administered. These alerts occur relatively infrequently compared to the total number of drugs dispensed. However, the Ministry report showed that, in 2006, 91% of the more than 18,000 level-1 alerts were overridden by pharmacies and dispensed to residents at 421 homes. We also found that 90% of the more than 700,000 level-2 alerts were overridden and dispensed in 2006. While level-2 alerts are less serious, there is still a risk of severe adverse reactions from the drug interaction. We further noted that at four homes (which did not include any of the three homes we visited), level-2 alerts were generated and overridden for at least 20% of all drugs dispensed, as compared to a median of 3% for all homes.

We acknowledge that in these instances pharmacists may have contacted the prescribing physician to obtain approval to override the alert. As well, many of these alerts may simply be repeat or otherwise unnecessary warnings because, for example, the Ministry's system generates the same notice each time a prescription is filled, even if the resident has tolerated the drug combination and it has previously been overridden by the pharmacist. However, the Ministry was not able to determine the number of unique alerts. Therefore, although the Ministry's system may exaggerate the incidence of alert overrides, this remains a concern both given the high number of alert overrides noted and the incidence of under-reporting of adverse drug reactions previously noted.

As well, while recognizing that medications are prescribed and dispensed by health-care professionals, we believe the Ministry, in collaboration with the College of Physicians and Surgeons of Ontario, should periodically monitor override data and follow up if the frequency of unique overrides seems high.

## RECOMMENDATION 2

To help reduce the risk of adverse medication reactions in residents, long-term-care homes should:

- ensure that residents more likely to experience adverse reactions—those taking a new higher-risk medication, for example—are monitored more closely than other residents and that results of this monitoring are documented;
- develop and implement policies to ensure consistent identification and documentation of adverse drug reactions, so that action can be taken to prevent future occurrences; and
- adopt consistent criteria for referring residents to specialized psychogeriatric programs and ensure that sufficient staff are appropriately trained in those criteria.

In addition, the Ministry of Health and Long-Term Care, in collaboration with the College of Physicians and Surgeons of Ontario (CPSO), should periodically review the use of higher-risk drugs at long-term-care homes, as well as the frequency with which residents receive drugs with unique drug-to-drug interaction alerts, or alternatively provide access to this information to the CPSO and other appropriate regulatory bodies so that appropriate follow-up action can be taken where the use of higher-risk drugs and the frequency of pharmacist overrides of alerts seem unduly high.

## SUMMARY OF LONG-TERM-CARE HOMES' RESPONSES

The homes generally supported this recommendation. One home indicated that it was now more closely monitoring residents who were at a higher risk of adverse drug reactions in addition to other high-risk individuals, such as new residents. As well, this home had established practices to address the consistent identification and documentation of adverse drug reactions and had criteria in place for referring residents to specialized psychogeriatric programs. Two of the homes highlighted that they were taking advantage of Ministry-funded opportunities to increase the number of staff with specialized training provided by psychogeriatric consultants in the community, as well as providing staff with a variety of related training initiatives, including medication monitoring. The third home indicated that it thought the Ministry should make specialized training available for selected nurses in long-term-care homes, and commented that at the time of its response the Ministry was providing little funding to train staff. This home also noted that retaining staff with this specialized training was difficult, as these people often sought positions elsewhere.

## MINISTRY RESPONSE

The Ministry supports the first part of this recommendation and will work with long-term-care homes and other partners, such as Local Health Integration Networks, to identify opportunities to better help them meet all aspects of this recommendation. The common resident assessment system, now being implemented in 25% of the homes, supports the improvement of medication-management practices both at the level of the individual home and system-wide across all homes. This system will ensure that homes have drug-related quality indicators to allow care providers to identify those residents at potentially higher risk who should receive increased monitoring related to medication effects. The system will also generate resident outcome reports, which would include medication management. As well, the Ministry has identified opportunities for collaboration with the Institute for Safe Medication Practices Canada (Institute) on its self-assessment tool for long-term-care homes. This will help homes identify opportunities for improvement with regard to medication management. The Ministry intends to work collaboratively with the Institute to encourage long-term-care homes to take advantage of this initiative.

The Ministry notes that issues pertaining to specific prescribing practices are matters of professional practice and within the purview of the prescribing physician. The Ministry relies on the professional judgment of regulated health professionals in determining the type and extent of medications required by individual residents. However, the Ministry recognizes the potential for risk surrounding multiple medications, especially among seniors, and supports the sharing of information and collaborative care models of the regulated professionals in this area.

## SAFEGUARDING MEDICATIONS

### Controlling Access to Medications

Regulations under the *Nursing Homes Act* and the *Charitable Institutions Act* require that medications be locked in cabinets (such as medication carts), storerooms, or, if applicable, refrigerators. Locking up medications helps prevent inappropriate access by residents, staff, or others in the home. We found that the homes we visited stored most prescription drugs in medication carts, which are used throughout the homes to assist nursing staff in delivering drugs to residents.

### Keys and Codes to Access Medications

We found that none of the homes we visited had documented policies regarding which staff should have keys to access medications. We found that none of the homes maintained a record of which staff were assigned which keys.

One of the homes used numerical keypad combination locks on three of its six medication carts, which had been provided by their contracted pharmacy. This would be a good control if each individual could be assigned a unique combination as it would help track the persons who had access to carts. However, the carts at this home did not have this capability. In fact, we found that two of these carts used the same access code, and that all nursing staff working on each wing of the home were provided with the same code. Furthermore, we were informed that a master code, allowing access to the three carts, was posted in medication rooms. Consequently, approximately 30 nurses and others who had access to the medication room could use the master code to unlock any of these carts at any time while leaving no record of their access.

### Locking Medication Rooms

The medication rooms at the homes we visited were used primarily to store medications supplied

by the Ontario Government Pharmaceutical and Medical Supply Service. The rooms also housed drugs awaiting destruction, medication carts not in use, and those drugs requiring refrigeration. One of the homes indicated that senior management performed periodic checks to ensure that medication rooms were locked. However, there was no documentation of the frequency or results of these checks. The other two homes did not have policies to conduct regular checks.

### Locking Narcotics and Other Controlled Substances

A regulation under the *Nursing Homes Act* requires that narcotics be stored under double-lock (for example, locked in a compartment within a locked medication cart). However, under the *Charitable Institutions Act*, other controlled substances are also required to be double-locked. We found that all the homes we visited had general policies for double-locking narcotics.

Health Canada classifies certain drugs, including narcotics, as controlled substances. According to Health Canada, controlled substances are “any type of drug that the federal government has categorized as having a higher-than-average potential for abuse or addiction.... Controlled substances range from illegal street drugs to prescription medications.” One type of controlled substance that was frequently administered in the homes we visited is benzodiazepines, which may be prescribed as a sedative or to ease anxiety. However, the homes all handled these drugs in the same way as other non-narcotic drugs because there was no requirement for additional security measures. Therefore, benzodiazepines may be readily accessible if a medication cart is left unlocked and unattended. In addition, we noted instances at two homes where benzodiazepines were missing from the emergency drug stock and could not be accounted for.

### Tracking Medication Use

According to the Ministry’s *Long-Term Care Homes Program Manual*, all medications administered to a resident should be recorded. The homes we visited generally required the nurse to document medication taken by a resident on the resident’s medication-administration record. If a medication is not administered (for example, the resident refuses the drug) the homes also require this to be recorded on the resident’s medication-administration record. For medications not received in weekly “strip packaging,” as well as for narcotics and other drugs that may be more susceptible to theft, periodic reconciliation of the medications administered with the medications received and those remaining helps provide assurance that drugs have not been misappropriated or wasted, and that the resident’s medication-administration record is accurate.

At all of the homes we visited, nursing staff were to record the administration of narcotics on the resident’s individual medication-administration record. They would then note the decrease in the quantity on hand on the narcotic-medication record stored with the remaining narcotics. Two of the homes also used a shift-change narcotics-count sheet, showing the number of narcotics on hand for each resident on a particular floor or wing of the home. The nurse going off shift and the one coming on duty both signed the count sheet, indicating their agreement with the quantity of narcotics on hand. We found these forms were generally completed at the homes we visited. However, none of the homes performed periodic test checks to ensure that these different records could be reconciled. One home’s pharmacist did indicate that, in some cases, the pharmacy would reconcile a resident’s individual narcotic sheet with the narcotic shift-change count and, in the event of a discrepancy, compare these tallies with the medication-administration record. However, we did not see any documentation that this had been done during 2006 or the first few months of 2007.

As the homes did not periodically reconcile these narcotics records, we reviewed a sample of medication-administration records, narcotic-medication records, and shift-change narcotics-count sheets where used. We noted discrepancies between these records at all of the homes. For example, we noted an instance where the resident's medication-administration record was signed showing that narcotic pills had been administered even though the shift-change count sheet said there were no pills available. We also noted an instance where the shift-change narcotics-count sheet decreased by more pills than had been dispensed according to the medication-administration record.

While Canadian federal legislation is not as explicit in requiring specific procedures to be conducted, we noted that legislation in the state of Michigan requires in-patient health facilities with pharmacy services to keep records on the number of doses dispensed for all controlled substances. Michigan also requires that a physical inventory count be conducted each year, and that the status be determined of any discrepancies between this inventory and acquisition and dispensing records.

### RECOMMENDATION 3

To better safeguard medications against possible theft or accidental misuse, long-term-care homes should:

- ensure that staff access to drugs is limited as much as practicable, and in accordance with legislation and standards, regardless of where the medications are stored; and
- periodically reconcile records of drugs administered with those received and on hand for narcotics and other drugs that may be more susceptible to theft (such as benzodiazepines), and take immediate follow-up action if the reconciliations indicate unaccounted-for narcotics.

### SUMMARY OF LONG-TERM-CARE HOMES' RESPONSES

The homes generally concurred with this recommendation. However, one home highlighted that guidelines alone would not prevent theft of medications, and therefore was considering establishing a process to follow in the event of a suspected theft, to help catch the perpetrator.

Another home indicated that, to further improve its safeguarding of medications, it has now implemented a process to sign out extra keys used by registered nurses to access medications. In addition, this home indicated that it was now reconciling medication records for narcotics on a regular basis and that it would review, in collaboration with its contracted pharmacy, the viability of periodically reconciling records for other medications more susceptible to theft. The home indicated that electronic processes may assist with this, as the tracking process can be difficult.

The third home stated that it was collaborating with its contracted pharmacy to research medication carts and determine which carts were the safest for medication administration in long-term-care homes. Furthermore, the home, in collaboration with its contracted pharmacist, was developing a process for reconciling narcotic control sheets with resident medication-administration records at a defined interval that meets best practice standards.

### MINISTRY RESPONSE

The Ministry supports this recommendation and will work with long-term-care homes and other partners, such as Local Health Integration Networks, to identify opportunities to better help long-term-care homes meet this recommendation.

## EXPIRED MEDICATIONS

Most medications have a limited life, after which they generally become less effective. In some cases, they may even cause new adverse reactions after expiry. All of the homes we visited had policies on checking to ensure that medications were still current, although one home's policy was not documented. As well, while one home indicated that medications should be checked monthly, the two others did not have an established frequency for verifying that drugs had not expired. We were informed that a consultant from each home's pharmacy also performed spot checks to ensure that medication had not expired, although this process was not documented in one home.

### Multi-Dose Medication Containers

At the homes we visited, most medications dispensed by the pharmacy were administered to residents within a week. However, some residents were prescribed drugs such as eye drops, inhalers, and nasal sprays that come in multi-dose containers and are administered on a daily or as-needed basis. These medications have a "best-before" date while sealed and generally expire within a specific number of days after being opened. Such medications, when prescribed for daily use, would generally be fully used up prior to expiry. However, drugs prescribed on an as-needed basis are at greater risk of expiring before they are fully used up because they are usually taken irregularly.

Two of the homes we visited had a policy of recording on the container the date that medications such as eye drops, inhalers, and nasal sprays were opened to ensure that they would be disposed of before expiry. Because these medications can expire at different times after opening—for example, some after one month, others after three months—the practice at one home was, in certain instances, also to record the date for disposal on the container. At these two homes, we reviewed

medication carts used to secure and store medications for administration to residents. We found that, while one home recorded the opening date on almost all of these products in accordance with its policy, the other recorded the opening date on only half the inhalers and eye drops that we reviewed. We also noted that several inhalers at one of these homes had expired between one and three months prior to our review. Furthermore, in some cases, the expired medications had been administered to residents.

The third home relied on the pre-printed "best-before" dates to determine whether eye drops, inhalers, and nasal sprays had expired. We could therefore not assess whether medications in its carts had expired on the basis of when they were opened. However, we noted a couple of instances where the medications had passed their printed "best-before" date. As well, the "best-before" date could not be seen on about one-third of the medications we reviewed because it was covered by a pharmacy label, so neither the home's staff nor we could readily determine whether these medications had expired.

### Emergency Drug Stock

Long-term-care homes generally stock certain medications to meet emergency needs of residents. Homes select these medications with input from their pharmacist and sometimes from a physician, and the physician may approve the medications in the emergency drug box. All of the homes we visited maintained an emergency drug stock containing between 20 and 50 different medications or dosages. Two of the homes included narcotics in their emergency drugs. As well, all three homes had policies on reviewing the emergency drugs, ranging from monthly or quarterly to "regularly," to ensure that they had not expired and were still appropriate for resident needs. Use of these emergency drugs ranged between 40 and 200 times a year, varying with the size of the home.

We reviewed the emergency drug stock at the homes we visited and noted the following:

- At one home, the emergency stock was complete with no expired drugs.
- At one of the other homes, we found that almost 30% of the different types of emergency drugs had expired—in one case, the medication had expired 10 months earlier. As well, two drugs on the emergency list were not stocked and another five were not maintained at pre-defined minimum quantities. There was no documentation to show when the emergency drug stock had last been reviewed to ensure its completeness and appropriateness.
- At the third home, no minimum and maximum quantities had been established for about 55% of emergency medications, including five narcotic drugs, two of which were stored in various dosages. Where minimum quantities had been established, more than half of these emergency medications were below the minimum level at the time of our audit. We further noted instances where there were two or fewer pills of certain emergency drugs for as long as two to four weeks before they were replenished.

### Ontario Government Pharmaceutical and Medical Supply Service

The Ontario Government Pharmaceutical and Medical Supply Service (Service) provides certain drugs, such as acetaminophen (generic Tylenol), cough medicine, laxatives, and vitamins free of charge to long-term-care homes for their residents. For the most part, these drugs are administered to residents only if a doctor has prescribed their use. There is no limit on the quantities of these drugs a home can order from the Service, and the Ministry does not monitor the extent to which long-term-care homes use the drugs for their residents. In addition, the long-term-care homes we visited

did not monitor the extent to which these drugs were used. At these homes, drugs received from the Service were stored in a medication room and, in one case, in the office of the home's director of care. In general, nursing staff obtained bottles of pills from storage, and kept them in their medication cart or another secure area in their unit of the home for easy access when required. One home indicated that nurses had previously stocked up on drugs for their particular unit of the home, resulting in medications expiring unused because there were more on hand than required to meet resident needs. This home therefore implemented maximum order quantities to help reduce overstocking of medications.

Drugs received by the homes free of charge from the Service were generally supplied in large quantities and not designated for a specific resident. Each of the homes had different policies and practices for determining how much medication to order from the Service. However, none of the homes had a process to reasonably estimate the drugs they needed from the Service when they needed them.

We reviewed drugs from the Service and found that all homes we visited had expired medications continuing to be stored alongside similar medications awaiting resident use. At one home, some bottles of one type of medication had expired four months earlier and two other types of medications were more than a year past their expiry date. Furthermore, none of the homes had consistently monitored the extent to which these drugs expired before they were used to better ensure that they order only what they need in future.

### RECOMMENDATION 4

To help ensure that residents receive safe and effective medications, long-term-care homes should implement processes to ensure that medications approaching expiry are identified and removed from use upon expiry.

In addition, to ensure that adequate (but not excessive) levels of medications are available when needed, long-term-care homes should establish minimum reorder levels and maximum order quantities for medications in the emergency drug stock and for medications supplied by the Ontario Government Pharmaceutical and Medical Supply Service in accordance with resident usage.

### SUMMARY OF LONG-TERM-CARE HOMES' RESPONSES

The homes generally supported the recommendation. One home commented that, in conjunction with its contracted pharmacy, it has reviewed and revised its process for inspecting and removing from use medications approaching expiry. Furthermore, this home indicated that related ongoing education and training would be provided to staff. Another home indicated that it was planning to implement a verification process to identify and remove from use medication that was approaching its expiry date. The third home commented that it has developed a process to review its Ontario Government Pharmaceutical and Medical Supply Service medications on a monthly basis for expired items. In addition, the home intended to collaborate with its contracted pharmacy in investigating best practices for determining the expiry of medications in multi-dose containers, such as eye drops and inhalers, once they were opened, and planned to make a recommendation to its Pharmacy and Therapeutics Committee based on best practice standards.

With respect to medications supplied by the Ontario Government Pharmaceutical and Medical Supply Service, one home indicated that it was now monitoring orders and following up when order quantities increased. It also indicated that the implementation of strip

packaging has decreased the need for large quantities of oral tablet medications to be kept at the home. Another home commented that its Professional Advisory Committee would complete a review of its emergency drug stock.

### MINISTRY RESPONSE

The Ministry supports this recommendation and will work with long-term-care homes and other partners, such as the Local Health Integration Networks, to identify opportunities to better help long-term-care homes meet this recommendation.

### DESTRUCTION OF EXCESS MEDICATION

Excess quantities of medications occur at long-term-care homes when drugs dispensed by the pharmacy or supplied by the Ontario Government Pharmaceutical and Medical Supply Service (Service) are not administered to a resident. This can happen, for example, when changes are made to a resident's treatment plan, when medications expire prior to use, or on the death or discharge of a resident.

#### Safeguarding Drugs to be Destroyed

At the three homes we visited, discontinued drugs awaiting destruction, including narcotics, were generally kept locked. While larger quantities of narcotics were locked in a separate compartment in the medication room, carts, or senior management's office, other drugs and smaller quantities of narcotics (a three-day supply or less) were generally kept in unlocked bins in a locked medication room.

## Responsible Disposal of Excess Medication

The *Nursing Homes Act* and the *Charitable Institutions Act* both require that excess medication resulting from a resident's discharge or death be recorded and destroyed. As well, the *Nursing Homes Act* requires the destruction of excess medication resulting from a change in a resident's drugs. Destruction records are to include details such as the resident's name, the drug name, the reason for destruction, and the date of destruction.

All the homes we visited had policies to destroy excess medication arising from these and other situations. We found that two of the homes we visited also had their own documented policies indicating that all drugs to be destroyed, including those that were discontinued, were to be tracked. However, none of the homes consistently recorded all the information required under legislation or by their own policies on medication destruction. At one home, for example, more than half of the approximately 400 recorded entries for drug disposal did not include all the required information.

Legislation also requires that a nurse and, generally, either a pharmacist or physician be present when drugs are destroyed. At the homes we visited, the director of care, who is a nurse, and the home's pharmacist generally oversaw the destruction process. Senior staff in two of the homes indicated that overseeing the destruction process was time-consuming because drugs had to be removed from their packaging and generally matched to the list of drugs to be destroyed. They said their time could be more effectively used on direct resident-care activities within the home. The third home had contracted with a biohazard waste company to remove their medications and destroy them, with no requirement for the home or pharmacist to remove medication from its packaging in advance. We noted that the homes may destroy significant quantities of medications. For example, our review of the destruction records at one of the homes we

visited indicated that more than 1,000 narcotics pills were destroyed in four months in 2006.

Nurses at two of the homes we visited were responsible for providing excess narcotics to senior management for destruction. At the third home, surplus narcotics in excess of a three-day supply were double-locked in medication carts until they could be collected by senior management for destruction. Smaller quantities were stored in unlocked bins in the medication room. However, we noted that there were no controls at any of the homes to ensure that all excess narcotics were forwarded to senior management or otherwise stored as required. For example, we found that senior management at the homes did not periodically compare information on their narcotic tracking forms to ensure that they had received all excess quantities of narcotics. We selected a sample of such forms and found instances where we would have expected narcotics to be on the destruction list, but they were not. For example, we identified one resident who had morphine administered on an as-needed basis. However, the list of drugs to be destroyed upon the resident's death did not include the remaining morphine pills, nor was there any record of the drugs having been destroyed.

The National Association of Pharmacy Regulatory Authorities (NAPRA) has noted that unused drugs can be made available to developing countries through various programs, and that the World Health Organization has published guidelines for drug donations. Also, provincial regulations in Manitoba permit drugs in sealed unopened containers to be repackaged for another person in certain circumstances. However, Ontario does not allow the repackaging or the donation to a developing country of unopened drugs resulting from a resident's discharge or death or, in the case of nursing homes, from a change of a resident's medications, because legislation requires the destruction of these drugs.

The Ontario College of Pharmacists' *Standards for Pharmacists Providing Pharmacy Services to Licensed Long Term Care Facilities* notes the importance of ensuring compliance with environmental requirements and ethical principles when destroying drugs in a long-term-care home. It also says the destruction should be conducted in an environmentally appropriate manner. Although all of the homes we visited had policies requiring the documentation of destroyed medication, and one indicated how frequently drugs should be destroyed, none had a documented policy on *how* drugs were to be destroyed. Furthermore, our interviews with nursing staff indicated that, at two of the homes, medications (including narcotics) were not always disposed of in an environmentally responsible manner, with wasted pills (for example, pills accidentally dropped on the floor) sometimes being discarded in the regular garbage. As well, injectable narcotics were disposed of in a variety of ways. We were informed by nursing staff at one of these two homes that these methods included squirting the residual contents into a tissue and throwing the tissue into the garbage, depositing the opened vial and its contents in a disposal container for syringes and other sharp objects, and taking the unused contents of the vial to the director of care. At the other home, injectable narcotics were sometimes deposited in a disposal container for sharp objects or poured down the drain. The Environmental Commissioner of Ontario's 2004–2005 Annual Report indicated that pharmaceuticals in Ontario waterways have the potential for significant environmental impacts.

### Reviewing Medication Waste

The Ministry's *Long-Term Care Homes Program Manual* notes that a home's pharmacy and therapeutics committee—which, at the homes we visited, included the pharmacist, director of care, and

administrator—should be responsible for reviewing drug-destruction records to identify and make recommendations about any unnecessary waste. However, none of the homes we visited had assessed the extent of waste from excess medications or expired medications, or the extent to which medications are wasted through, for example, accidental spills.

Prior to June 2006, homes had the option of returning expired medications originally received from the Ontario Government Pharmaceutical and Medical Supply Service back to the Service for destruction. The Ministry said the Service stopped accepting these returns after some homes sent back medications that did not originate with the Service, as well as syringes, laboratory samples, and other items that they should have disposed of themselves.

### RECOMMENDATION 5

To help minimize medication waste and potential misappropriation, as well as to promote the efficient and environmentally responsible disposal of excess medication, long-term-care homes should:

- in conjunction with the Ministry of Health and Long-Term Care and the Local Health Integration Networks, review ways to streamline the drug-tracking and -destruction process while retaining sufficient safeguards over this process; and
- periodically monitor staff to ensure that they are following accepted policies for disposing of expired and excess medication.

While developing regulations for Bill 140 (the new act on long-term-care homes), the Ministry of Health and Long-Term Care should also consider the feasibility of alternatives such as those used in other jurisdictions with respect to the destruction of unopened packaged medications that are still usable.

## SUMMARY OF LONG-TERM-CARE HOMES' RESPONSES

The homes generally supported this recommendation, and one home indicated that it had a well-established drug-destruction process in place that is a responsibility shared between the home and its contracted pharmacy. It also commented that an electronic tracking process would enable the home to share information and produce meaningful reports that would benefit its residents. Another home indicated that, although the current process was time-consuming, it was necessary in order to meet required standards. This home also indicated that, in conjunction with its contracted pharmacy, it was determining the viability of using a bar-coding system to track medications better while enhancing security and accountability. As well, the home noted that more frequent destruction of medications may help to reduce the risk of misappropriation, and expressed an interest in participating on a working committee with the Ministry of Health and Long-Term Care to review ways to streamline the drug-tracking and destruction process.

Furthermore, one of the homes recommended that environmentally sound disposal of medications should be in place across all health-care settings. This home also commented that it has updated its existing policy to include safe disposal methods for all medications. Another home indicated that it would further strengthen its staff training on the disposal of medications.

## MINISTRY RESPONSE

The Ministry supports this recommendation and will work with long-term-care homes and other partners, such as Local Health Integration Networks, to identify opportunities to better help long-term-care homes meet this recommendation.

As well, the Ministry will consider the feasibility of alternatives to the destruction of unopened packaged medications when developing regulations for Bill 140. This will involve reviewing practices in Ontario and other jurisdictions, and working with the Ministry's partners.