ONTARIO PHARMACISTS ASSOCIATION

OPA TELEPHONE TOWN HALL MEETINGS AND FREQUENTLY ASKED QUESTIONS

(Last updated October 1, 2015)

The Ontario government is facing an unprecedented deficit , and virtually all areas of the Ontario economy, including the entire healthcare sector, are facing funding cutbacks as a result of efforts to control, or eradicate, it.

In the April 2015 budget, reductions in Ontario Public Drug Program (OPDP) expenditures were targeted at $200M annually, with about $150M to come directly from community and long-term care pharmacy funding. The savings, which are guaranteed savings, could have very easily been obtained through a drastic dispensing fee reduction (similar to what we saw happen with Ontario physicians). Instead, the Ministry opted to work with the Association to obtain the savings through the enforcement and strengthening of current regulations and policies.

It is difficult to argue that bi-weekly or monthly dispensing of medications to stable, uncomplicated and well-controlled patients, while economically good for business, is unsustainable and clinically indefensible. Therefore, it is OPA's recommendation to all pharmacists and pharmacy owners to uphold the intent of the new regulations and to drive the overall savings to the Ministry in order to prevent a much larger cut downstream – for example a broad-based ODB dispensing fee reduction.

Pharmacies are strongly urged to not seek workarounds to the changes coming into force on October 1, 2015. Every time a pharmacy applies an exemption for a patient's chronic medication dispensing, overall savings targets become more and more diluted, possibly paving the way to an imposed ODB fee reduction to get the Ministry's guaranteed savings.

The Ontario Pharmacists Association firmly believes that complying with these changes, while not ideal, will show good faith and will work toward longer-term gains for the industry and health care overall.

To assist pharmacists in preparing for, and implementing these changes, OPA hosted two telephone town halls in late September/early October. Below is a summary of the questions asked and answers provided.

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QUESTIONS AND ANSWERS:

1. **How is the Ministry communicating these changes to physicians and the public so the burden of explanation does not fall on the shoulders of pharmacists?**

   The Ministry has communicated with the Ontario Medical Association directly and has created a fact sheet for both physicians and the public. OPA has also been meeting with senior OMA representatives to seek their collaboration on these and other initiatives in an effort to present a collaborative front with all Ontarians. That said, it is not known how well communications on these initiatives and the regulatory changes that are driving them have reached the medical community at the grassroots. And so we can assume that there will still be the added burden on pharmacy team members (technicians included) to inform physicians and patients of the changes.

   The Ontario Pharmacists Association is working with the Ministry on templates documents (e.g., tear pads, bag stuffers, signage for pharmacies and physician offices) to help explain the changes that may impact delivery of your services.

2. **How can we compensate the loss of revenue due to this change?**

   The Ontario Pharmacists Association is aware of the large financial and operational impacts these changes will have on individual community and LTC pharmacies and the profession as a whole. OPA has been working hard for many years to assist business owners in finding alternative means to compete, drive their businesses and expanding into new and sustainable practice offerings while not compromising the valuable services that pharmacies and pharmacists offer.

   The OPA Suggested Fee Guide for Uninsured Professional Pharmacy Services was developed to assist in the creation of new revenue streams that would not rely on the public payor. Continued reliance of dispensing revenues to drive the business is long out-of-date as payors, in general, are looking for trimming their expenditures. Similarly, OPA has strongly advocated that its members refrain from waiving copayments, as such strategies, originally aimed at protecting market share, are fundamentally flawed. Waiving copayments effectively has pharmacists doing more work for no compensation, and these changes greatly exacerbate the losses.

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QUESTIONS AND ANSWERS ON NO SUBSTITUTION:

3. **With respect to the new regulations regarding "No Substitution", will patients who already get a brand name medication using the 'no sub' clause be grandfathered even if the brand name has more than one interchangeable generic?**

   On September 18, 2015, the Ministry announced the formal approval by Cabinet of the regulations to the ODBA and DIDFA. Included in the approval was a change that would:

   > *[E]xempt extemporaneous preparations and drugs supplied to patients on complex medical regimens from the five dispensing fees per 365-day period rule to reflect that more frequent dispensing is required in these cases; and* ***grandparent patients who are entitled to have brand products reimbursed as "No Substitution" claims under existing program rules****.*

   This means that if a patient is currently receiving the branded pharmaceutical product pursuant to the original rules for "No Substitution" (i.e., that a valid ADR is on file for the one generic product tried), then there is no need to move back to a second generic. Moving forward, the new two-generic rule with valid ADRs to both generics would apply for all patients (presuming more than one interchangeable generic exists).

QUESTIONS AND ANSWERS ON COMPLIANCE PACKAGING:

4. **What happens to patients currently on blister packaging?**

   There are two important facts to keep in mind:

   - For dispensing services, the Ministry only pays on three components – drug cost, markup, and dispensing fee.
   - Blister packaging is actually an unfunded professional service which has never been funded by the Ministry.

   Stated simply, nothing happens to blister pack patients. Blister packaging can continue, but pharmacists will need to determine on their own how to sustain the

service, especially for those who really only participated in the service for matters of convenience.

Up until now, for most chronic medications, pharmacists would fill or refill all of the compliance pack prescriptions at the same time for the same number of days' supply (in most cases either in biweekly or every four weeks), and collect up to two dispensing fees per calendar month for each prescription. With a small selection of exempted (more fragile) medications like antipsychotics, it was possible to collect weekly, and in some cases, daily fees if warranted.

Technically speaking, compliance packaging as a professional service has been sustained in one of two ways: as a billable professional service with either a monthly or annual fee, or through the revenues generated from the frequently paid dispensing fees. With the latter, many pharmacies simply chose not to charge patients directly for the service, instead opting to absorb the costs internally. But one could suggest that these costs were offset by the multiple fees.

With the new five-fee cap for chronic medications, the status quo changes because the fees you may be relying on to cover service costs are largely drying up, unless the patient meets specific criteria to exempt them. What this means is that blister packaging becomes more of a cognitive service, because pharmacists will have to determine if their patient qualifies for more frequent dispensing than what the rules stipulate and, if yes, then the pharmacist will need to document and rationalize their professional decision, obtain patient consent and notify the appropriate prescriber (or prescribers if more than one). Lastly, and this is because software requirements are not yet in place, pharmacists will need to manually track and document each chronic medication dispensed as an eligible transaction warranting more frequent dispensing. For patients who don't qualify for one of the exemptions, the pharmacist will need to seek alternate mechanisms to fund the compliance pack service, because after the fifth dispense for each chronic prescription, the pharmacy is on its own.

The Ministry has made it abundantly clear that due to the size of the provincial deficit, they can no longer afford to pay more frequent fees unless absolutely warranted. It is not that they don't see the value in more frequent dispensing when a patient truly needs it – it is more that they will no longer pay for unwarranted high frequency dispensing.

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5. How do the new regulations affect blister pack patients?

Technically, the new regulations do not affect blister-pack patients, rather impact frequency of dispensing which in turn impacts how services such as blister packaging are administered and financially sustained.

For patients who have a defined impairment (physical, cognitive or sensory) or who are on a complex medication regimen, the regulations will not block more frequent dispensing. (With respect to a physical impairment, it will need to be one that impacts a patient's ability to safely self-administer their medications.) For patients who do not meet these criteria, a more formal discussion with them is recommended to obtain their consent for more frequent dispensing if the pharmacy chooses to initiate a new service fee, perhaps using the OPA Suggested Fee Guide.

It is important to note that for these ineligible patients, pharmacies are not permitted to pass on ineligible dispensing fees to patients (that is, fees beyond the fifth dispensing transaction). And if there is no fee that is eligible, then there is no copayment. This is where documentation of each dispense will be critical, since there will be no ability for the Ministry's Health Network System to indicate that the fee cap has been reached. After the fifth transaction, pharmacists will still see the fee go through and be paid and copayments assessed. These "paid" fees will be recovered by the Ministry on audit and copayments collected from patients will need to be refunded. Although the Ministry will not be able to monitor and appropriately adjudicate in real time until the HNS changes are implemented in June 2016, it will be closely monitoring transactions behind the scenes and will be able to perform audit and recoveries retroactive to October 1, 2015.

6. How do we manage chronic medication dispensing for patients on an ODB monthly card?

There has been a lot of confusion regarding Ontario Works patients and paper card holders, in general. Not all paper card holders are exempt. This section will provide you with some clarity on the matter:

- **Ontario Works** (OW) patients are those who currently possess cards that are issued monthly, and as such, they are limited to a 35-day day supply.

  - OntarioWorks (D, K, L, M. N and Y cards) patients are **EXEMPT** from the 5/365 rule.
    - D- and M- cards are the most commonly seen prefixes for OW patients
  - Biweekly or monthly dispensing is permitted (maximum of two dispenses per calendar month)
- **Ontario Disability Support Program** (ODSP) patients are those who currently possess a C-card. These patients can receive up to a 100-day supply.
  - ODSP (C-card) patients are **NOT EXEMPT**
  - The 5/365 rule applies.
- **Home Care** patients are those who currently possess a P-card. These patients can receive up to a 100-day supply.
  - Home Care (P-card) patients are **NOT EXEMPT**
  - The 5/365 rule applies.

7. How do we notify ODB if we have proper documentation for more frequent dispensing, in order to prevent future audit/clawback?

There is no need to notify ODB; all documentation is required to be stored as a permanent part of the patient record just like all other forms of documentation. To prevent future audits and recoveries, OPA has created a template form for every pharmacy to use. It is an all-in-one form that covers all of the key required elements including the clinical decision, express consent of the patient or their agent, and notification of the prescriber:

- Pharmacist's Decision – identify and provide the rationale for one of the identified impairments or to declare the presence of a complex medication regimen.
- Patient/Agent Consent – this is required consent for more frequent dispensing, recognizing that if the patient qualifies, there will be a fee that will be passed on to the Ministry which that means the patient will see their copayment continuing with each transaction. (This is not an "either/or" situation - patient consent in the absence of one of the exception criteria is not sufficient; the patient must first be eligible and then must sign the document.
- Prescriber Notification – It is important to know that pharmacists possess full authority to make these decisions and will therefore be accountable for the veracity and authenticity of those decisions. The requirement is simply notification of the prescriber or prescribers, if there is more than one. There is no need whatsoever for prescriber authorization, permission or even response.

Use of the form, by itself, is not an iron-clad form of protection against audits and recoveries; it merely tackles the pharmacist's documentation needs. Even with a fully completed form, if a clinical decision is either questionable or unsubstantiated, the pharmacy remains at risk of a recovery in the event of an audit. Therefore, it is crucial that any documented decision on the form is defensible.

8. When a claim is rejected for too many fees, will there be an override code to use for cases where extra fees are appropriate, such as compliance pack patients?

At this time and until the HNS changes are made, pharmacies will not see any rejections to fees. The HNS will continue to adjudicate all claims as usual (notwithstanding the two fees per calendar month rule, Response Code 87); please do NOT assume that adjudicated and paid fees won't get clawed back. If these claims are not properly substantiated with documentation, fees paid after the fifth dispense will be recovered by the Ministry pursuant to a manual audit.

The technical approach for overriding fee rejections will most likely be an Intervention Code process; however, this solution will not be in place until mid-2016, and will coincide with the time when real-time fee rejections will begin. Once again, at this time, real-time rejections and intervention codes are not yet operational and won't be until approximately June 2016.

Therefore, it is imperative that everyone on the pharmacy team understands the pharmacy's internal processes for tracking and identifying patients and individual chronic medication transactions.

- Independent operators or those without corporate head office direction should contact their pharmacy software provider for direction.
- Members of a larger corporate group, banner or chain may already have received recommended options or a defined process from their head office and are strongly encouraged to contact their head office for guidance.

For those seeking more information, the Ontario Pharmacists Association will be posting some best practices to its member website in the coming days, but we emphasize that owner, head office, or software vendor direction should be the primary guide.

The Association has been meeting regularly with pharmacy software vendors to help explain the regulatory changes and to suggest interim technical solutions that fit within the pharmacy workflow. These interim solutions may already be in place or will be by October 1, 2015. The Association is also working to facilitate a meeting between the Ministry and pharmacy software vendors to more smoothly navigate these matters. More direction will follow as OPA obtains more information on the technical HNS changes and our work with the vendor community.

9. **I am concerned about a handful of my patients that I only give monthly supplies to so I can better keep track of them. Most have a mild dementia and I worry about giving them large quantities.**

   As long as each patient qualifies under the patient-specific criteria then they can continue to receive smaller quantities (more frequent dispensing) as a matter of safety. In this case, for patients with mild dementia, the applicable criterion would be "cognitive impairment" and you would simply indicate this on the form and provide some background or supportive evidence of the impairment. Pharmacies would be required to maintain all appropriate documentation, including patient/agent consent and notification of the prescriber(s).

10. **We are not allowed to pass the fee to the patient past 5 fees. So what do I charge the patient that is currently paying $4.11/month per med for his monthly blister meds?**

    Under the *Ontario Drug Benefit Act*, there is a long-standing clause which states that a pharmacy cannot charge a patient a fee for an eligible drug product that the Executive Officer would not pay. This means pharmacists cannot pass on an ineligible fee.
    On the assumption that a patient does not qualify for an exemption, beyond the fifth dispense, pharmacies may no longer collect the $4.11/month/prescription as this appears to be part of the copayment. The application of a copayment is directly linked to the adjudication of a dispensing fee – so if there is no fee charged, then there can be no copayment charged.

    If not already an approach you have in place, you may want to consider converting your blister-pack patients to a professional service that is identified as such, with an annual or monthly fee that is fair and reasonable and is unattached to the electronic or manual submission of the dispensing transaction to the Ministry. Best practice

suggests that the pharmacist obtain patient/agent consent (as a form of a contract) for the service and the uninsured professional fee attributed to it.

11. What if the prescriber refuses to prescribe a 100-day supply for his/her patients because he/she chooses to have the patient come back for monthly visits?

The Ontario Pharmacists Association has raised this issue with the Ministry and it is something they will monitor over the coming months. The Ministry has communicated with the Ontario Medical Association to convey the new expectations of prescribers. However, there is nothing at this time that compels a physician to collaborate.

In OPA's August 24 submission to the proposed regulations, a request was made for an additional regulatory change that would permit the pharmacist to override prescribed quantities, enable the dispensing of maintenance supplies of up to 100 days, and drive compliance with the policy. OPA is pleased to see new language incorporated into the recently approved regulations, albeit with modifications, to effectively enable such quantity adjustments under certain circumstances.

In the event that a prescription directs the pharmacist to dispense a short-term quantity (ie/ a one-month supply), the pharmacist may override this quantity if there are sufficient refills on the prescription to do so. The simplest way to look at this is to calculate the total amount authorized on the prescription. That would be the amount of medication/doses that includes both the initial dispense AND all of the refills. Let's look at three different Rx presentations, recalling that our goal in each is 100 days' supply:

- Scenario 1: 30-day supply plus 0 refills = 1 x 30 = 30 days spanning the total Rx
    - Maximum amount that can be dispensed by the pharmacist is 30 days
    - No override is permissible here
- Scenario 2: 30-day supply plus 1 refill = 2 x 30 = 60 days spanning the total Rx
    - Maximum amount that can be dispensed by the pharmacist is 60 days
    - Override is permissible here but still we are short of the 100-day goal
- Scenario 3: 30-day supply plus 11 refills = 12 x 30 = 360 days spanning the total Rx
    - Maximum amount that can be dispensed by the pharmacist is 100 days
    - Override to goal amount of 100 days is permissible
    - Residual amount on the Rx of 260 days' supply

Pharmacists cannot exceed the entire amount authorized on the prescription – that is, the amount inclusive of all refills – but they are permitted to increase quantities up to a maximum of allowable by the Executive Officer (ie/ a three-month supply). In these cases, pharmacists must document on the prescription record that the quantity was increased to the maximum allowable days' supply as per the pharmacist's professional judgement provided the prescription has sufficient refills to account for the increased quantity dispensed.

If the total amount prescribed (inclusive of refills) does not enable a 100-day supply to be dispensed, then the pharmacist cannot override this quantity and must confer with the prescriber to increase the supply to maintenance levels.

We recognize that the regulatory change may not always help in managing prescriptions from short-course prescribers, such as walk-in clinic physicians/nurse practitioners and from whom quantities are often limited with no refills issued. In these cases, pharmacists are encouraged to continue in their efforts to engage these prescribers in a dialogue to shift prescribing practices toward maintenance supplies, and to subsequently document any prescriber resistance.

Notwithstanding all of the above, if the trade size of the chronic medication provides less than a 100-day supply, there is no expectation to "top up" that quantity. An example would include etidronate disodium/calcium carbonate which comes pre-packed as a 90-day supply.

12. Is the procedure for billing compliance patients the same as before?

Technically speaking, there is no set procedure for billing compliance patients. There has only been a process for billing claims in accordance with the rules related to the frequency of dispensing.

For patients meeting the criteria for more frequent dispensing, the rule of thumb is a maximum of two dispensing fees per calendar month. Exceptions to that rule continue to apply and are related to more sensitive therapies such as antipsychotics, antidepressants, narcotics, and others. This is based on the short-term dispensing policy of 2008 which permitted much more frequent dispensing regimens including daily and weekly.

For ineligible patients who continue to request compliance packaging as a matter of convenience, the 5 dispenses/365 days ("5/365") rule applies, beyond which only the cost of the drug plus mark-up may be billed. Additional costs associated with compliance packs in these cases can only be billed as an uninsured professional service fee to the patient, with patient consent, invoicing, and internal documentation to be implemented as best practice.

13. Is prednisone included in the chronic med list and why is warfarin included when often there are numerous changes based on INR fluctuations?

Neither prednisone nor warfarin are included on the list of chronic medications. In fact, both are listed on the Ministry's short term dispensing list (STDL), found here http://health.gov.on.ca/en/pro/programs/drugs/odbf/dispensing_fees_drug.pdf. However, for each of these products, there are some conditions that need to be considered:

- Prednisone falls under the category of "*21. Corticosteroids during periods of dosage tapering*"
- Warfarin falls under the category of "*3. Anticoagulants during periods of dosage adjustment*"

In other words, long-term, stable, and consistent dosing of either medication would not qualify for weekly dispensing under the short term dispensing policy. At the same time, neither medication is listed on the chronic medication list; as such, they would still both be eligible for more frequent dispensing of up to a maximum of twice per calendar month.

14. If a patient is getting their meds monthly by choice, but not in a blister, does that qualify as an exemption from the five dispensing fees per year rule?

No, it does not. The 5/365 role is strictly related to the frequency of dispensing; packaging is irrelevant with these regulations.

15. What happens when a prescriber indicates bi-weekly dosettes are to be used….do we still need to document our own reasons?

Simply documenting that the prescriber has ordered compliance packaging is insufficient. If the prescriber's intention is unclear, then the pharmacist is obligated to

contact the prescriber to ascertain why compliance packaging (and more frequent dispensing) has been ordered. If the prescriber's intent is clear and you concur, then document this as your rationale on the OPA form under "Pharmacist's Decision" and add a note to that section on the form that this is also pursuant to the prescriber's intent.

Remember that the prescriber may only be ordering such packaging for matters of patient convenience, which would not qualify the more frequent dispensing. Even if the patient does not qualify, they can still receive compliance packages. The pharmacist can therefore proceed with the prescriber's directive and is encouraged to apply a professional fee for the packaging service, pursuant of course to patient/agent consent. In obtaining this consent, pharmacists are urged to inform the patient that the prescriber's order for more frequent dispensing does not meet the criteria and to proceed with compliance packaging will require an additional service charge. Best practice suggests that you only proceed with express patient/agent consent.

16. Every year, Trillium starts to cut back days' supplies and/or patients sometimes want to cut their quantity because the deductible is high and may be too much to afford.

The limit of five annual dispensing fees on the 15 chronic-use drug categories does apply to Trillium recipients, but only once their deductible has been reached. Only claims submitted after the deductible has been met will be counted towards the five fee per 365 day period limit.

17. I read in the latest bulletin that OPA is developing tools for us to help deal with this new ODB process. Do you know if one of the tools is a letter regarding impairment that we will be able to send to prescribers?

The Association has created an all-in-one documentation/consent/notification form that will serve this purpose. It can be found on the OPA website under Resources/Tools and Forms/Frequency of Dispensing and Compliance Packaging.

Members are reminded that they do not need to seek authorization, permission or even a response from the prescriber for declaration of impairment or determination of "complex medication regimen". So long as your decisions are valid and defensible, that will be sufficient; your only requirement is "Prescriber Notification."

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18. Do prescribers still need to be notified if they were the ones who initiated the short-term dispensing?

Please refer to question #12.

If the prescriber initiates the short-term dispensing frequency and the rationale behind the order fits the patient criteria, then the answer is "Yes". While it may seem a duplication of effort and a waste of time, the notification of the prescriber is a requirement for the pharmacy to defend against an audit and prevent a recovery. If the practice were to be audited, the Ministry would not be going to the prescriber's office to cross-reference and validate the pharmacist's claim. The Ontario Pharmacists Association recommends adding the prescriber's direction into the appropriate exemption box.

In addition, and as a best practice, OPA recommends use of the documentation template even if not for an ODB claim purposes. For example, even if none of the patient-based criteria apply, the form can be used for consent purposes for compliance packaging/short-term dispensing for reasons of convenience.

19. How specific are the requirements re: cognitive, physical, sensory impairments?

Deliberately, there are no requirements or definitions associated with a declaration of an impairment. These are clinical declarations that are purposely left vague since every manifestation will be slightly different. To define it means to limit it, and this might inadvertently miss someone.

While not part of the question, the same critical thinking needs to be applied to a determination of "complex medication regimen." This is where pharmacists' clinical decision-making skills will be needed. In potential cases of an impairment or presence of a complex regimen, ask yourself this question – will patient safety and/or patient continuity of care truly be negatively impacted by dispensing larger quantities of medications?

- If the answer is "yes", then indicate this on the form and document your clinical rationale to dispense in smaller quantities.

- If the answer is “no”, such as the patient being wheelchair-bound (clearly a physical impairment, but not necessarily one that makes taking meds in chronic quantities problematic), then the impairment would not be defensible on audit.

With extremely broad-based and vague criteria, there may be an urge to rationalize shorter term dispensing. The Association strongly suggests that all pharmacists resist the urge to “seek opportunities” for short-term dispensing; instead, try to shift as many patients as possible to longer term, maintenance quantities for their chronic medications, so long as this does not put the patient at risk as a means of supporting the savings initiative. Looking for work-arounds will only dilute the savings the Ministry is seeking and will leave pharmacy vulnerable to much deeper funding cuts (i.e., broader ODB fee reductions) later on.

20. If vacationers forget their meds at home and only need a few days/weeks supply how does that affect their billing? Must I give 100 days? How can I if their supply shows too early fill?

Processing of vacation supplies should proceed as normal and all dispenses (vacation or otherwise) will be counted against the five fees per 365 days.

If we follow the intent of the regulations and assume that 100-day supplies are issued each time for chronic medications, then four dispenses will more than cover the 365-day period, leaving one additional dispense for any irregular occurrences such as lost medications. Dispensing in smaller than 100-day quantities will challenge that. At this time, there is no plan for an override code to enable payment of a sixth dispensing fee (unless of course a patient-based criterion applies).

Prior to hitting the fifth dispense, if you receive a days’ supply rejection, “Good Faith” intervention codes will continue to apply. Recall also that under pharmacists’ expanded scope of practice, and particularly pharmacist extensions of prescriptions, pharmacists do have the ability to assess a fair and reasonable administrative fee to the patient (not billable to the Ministry) if the prescription has exhausted all refills.

In the end, pharmacists are reminded that restriction of care is not an option. In other words, pharmacists cannot withhold a patient’s medication (and break their continuity of care) simply because a dispensing fee is not being paid. At all times, pharmacists are obligated under the Ontario College of Pharmacists Code of Ethics, Code of Conduct and Standard of Practice to do what is in the best interest of the patient.

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21. Do hospital discharge supplies count as part of the five fills or not since post discharge is inherently a non-stable chronic med period?

Yes. It is also important to note that the Ministry expects pharmacists to implement the Trial Prescription Program with initial fills of chronic medications (a 30-day trial of the chronic medication to assess tolerability and/or effectiveness). This dispense counts against the 5/365 (i.e., one Trial plus four dispenses at maintenance levels).

Before implementing the Trial, check back in the patient's profile to see if the medication has been used before, and/or inquire of the patient or agent to find out if that medication has been tried before (to the best of their recollection) and then document the decision to implement (or not implement) the Trial.

Support tools for the Trial Prescription Program are in development and will be available on the OPA website shortly.

22. Will there be override codes for circumstances that are not "normal" chronic filling periods such as post hospital discharge, vacation spot supplies, dosing changes (could show up as same DIN, but the doc is adjusting doses - how else will ODB know to still pay us after five times even if they have classified as a "chronic med"?)

At this time, aside from the patient-based criteria that includes the identified impairments and/or determination of a complex medication regimen, there are no planned overrides.
With respect to dosing changes, the Ministry has informed OPA that monitoring of frequency will be DIN-specific, meaning that:

- Dosing changes within the DIN (such as "same strength, but different dose") will not lead to a new dispensing count on the 5/365 rule.
- Changes in strength, meaning a new DIN, (such as "increase from 5mg daily to 10mg daily") will lead to a new dispensing count on the 5/365 rule.
- However, it should be noted that the intent of this policy is to ensure that the escalation in unwarranted short-term dispensing of chronic medications is curbed. While the monitoring will be DIN-specific, switching to an interchangeable brand of the chronic medication (technically changing the DIN), would be considered a work-around or loophole and would not likely survive an

audit. It is in everyone's best interest not to look for these work-arounds or loopholes in order to drive success of these cost-savings initiatives. The alternative would be dilution of the savings target and the possibility of deeper funding cuts to secure the Ministry's financial objectives.

The Association will be meeting regularly with the Ministry to assess the pharmacist, prescriber and patient experiences with these new changes over the next several months. OPA will be implementing a feedback mechanism to collect specific concerns and unforeseen challenges at the front line. Watch your eblasts or the website for more information.

23. Are we allowed to charge clients an administration charge for compliance packaging? If yes, can we base it on the number of medications the client uses?

From the Ministry's FAQ document for pharmacists:

> *"ODB recipients who require more frequent dispensing for a valid clinical reason will be able to qualify under the established exemptions. For all other ODB recipients who do not meet the established exemption criteria, the pharmacist shall not pass on any ODB-ineligible dispensing fees – that is, beyond the fifth dispensing transaction – to either the ODB recipient or their private insurer (if applicable). Passing new costs to ODB recipients is not the intent of this initiative."*

It is OPA's position that while passing on ineligible dispensing fees to patients and/or their private insurers is not permissible, the ability of the Ministry to restrict the assessment of a fair and reasonable fee for the uninsured professional service of compliance packaging is beyond their scope and control. Compliance packaging was never a service paid for by the Ministry as its funding formula only included formulary cost of the drug product, the maximum allowable mark-up and, where eligible, the prevailing ODB dispensing fee. Therefore, OPA recommends that pharmacists avail themselves of the OPA Suggested Fee Guide for Uninsured Professional Pharmacy Services (available on the OPA Members' Only website under the "Resources" tab) to assist in setting a fair and reasonable fee for this uninsured professional service.

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24. Will there be a way to track how many times someone has filed a chronic (applicable) med, especially if or is new to your pharmacy?

There are a variety of ways for pharmacies to track a patient's status against the 5/365 rule. Pharmacy owners, corporate head offices and/or pharmacy software providers may already have a mechanism for the pharmacy team to follow. The Association is developing a list of best practices that can serve as interim guides in the absence of other solutions. Check your eblasts and the OPA website for more information over the coming days.

25. What documentation covers pharmacies for patients with cognitive deficits who will be filled more frequently?

There are no formal guides or definitions to cover this or other impairments. Pharmacist decisions are to be made on a case-by-case basis, and can often be informed by the medications the patients are receiving. For example, certain medications may suggest that a patient has a cognitive disorder. If in doubt, the pharmacist is encouraged to consult with the prescriber to determine the most appropriate approach for the patient.

The bottom line should be whether the pharmacist truly feels that the patient is at risk if some or all of their medications are dispensed in large quantities.

26. Are nursing home residents exempt from the 5/365 rule?

Yes. Residents in formal long-term care (LTC) facilities are exempt due to their fragility and to LTC staff workflows processes. There are other mechanisms and initiatives that will address the savings targets for LTC pharmacies.

Similarly, patients residing in Homes for Special Care and other publicly-funded residential care facilities are also exempt from the 5/365 rule.

Since we have mentioned Homes for Special Care, it should be noted that claims for patients in these homes will not be subject to a dispensing fee reduction as seen with LTC pharmacy claims.

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27. How complex is a "complex medication regimen”?

Complex is in the eye of the beholder and therefore, these are clinical decisions that can really only be made on a case-by-case basis and which require every pharmacist to exercise due diligence and self-discipline so as not to sacrifice any progress on the savings targets.

For example, a pharmacy may have a patient on seven medications who has them all mixed up and as a result, adherence is poor and outcomes are not being seen. At the same time, the pharmacy may have another patient on the exact same seven medications who is exceptionally well controlled and is seeing positive results of therapy. For Patient 1, the regimen would clearly be complex, thereby requiring a clinical intervention in the form of compliance packaging and shorter dispensing with ongoing monitoring. To avoid a recovery, best practice would suggest that the pharmacist substantiate his/her rationale for short-term dispensing using refill records indicating broad-based, documented and routine non-adherence. Ongoing monitoring is required and might be a good case for a MedsCheck Annual and/or Follow-Up until such a time as control has been established. To quote the Ministry FAQ document:

> *ODB recipients who are deemed to require more frequent dispensing will need to be assessed regularly to verify an ongoing need for more frequent dispensing. For example, a patient on a complex medication regimen may require assistance for a short period of time, in order to learn to manage their medications as directed, but once stabilized, may be capable of managing 100-day supplies.*

For Patient 2, the regimen would not be deemed complex and, therefore, would not qualify for shorter-term dispensing. In the event of an audit, the pharmacist would likely be asked to substantiate his/her rationale for short-term dispensing using, for example, refill records and documented routine non-adherence. If there is no such evidence, a recovery would likely be the outcome of such an audit.

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28. If an ODB recipient is deemed incapable of managing his/her medications and proper documentation is on file to dispense weekly in a blister pack, what will be the fees paid for these "chronic-use" medications? Will the fees still only be the first two fees per month (as they are now) or will the fees be paid each week for these "chronic-use" medications?

With the exception of those medications identified on the Short Term Dispensing List (STDL) from 2008, the most frequent dispensing regimen is twice per calendar month. Only those meds on the STDL can be processed weekly with fees still in place. Access to the STDL can be found on the OPA website under the ”Resources/Tools and Forms/Frequency of Dispensing and Compliance Packaging” tab.

In general, for community pharmacy, fees will remain the same, seeing no differentiation for more frequency dispenses.

At this time, current protocols remain intact and all transactions should be appropriately documented, ideally within the transaction record and not in the patient profile note section. Once the technical solutions to the HNS are in place, it has been recommended that the first five dispenses be processed sequentially without a break, and intervention codes (likely available by June 2016) be used afterward. More details on these protocols will be provided as information becomes available.

29. Where it is not our fault for a patient getting more dispensings per year, e.g., a patient has left their medicine somewhere and need it, are we expected to provide pro-bono prescriptions or is there a way to document what has happened and submit and receive a proper fee?

If 100-day supplies are being provided, then the most dispenses a pharmacist will likely need will be four (which would cover a 400-day supply in total). In this case, a fifth dispense serves as a form of insurance to cover for any discrepancies such as lost medications. At this point in time, if the 5/365 day rule is in place, any dispense after the fifth transaction would only be reimbursed for formulary drug cost plus mark-up.

The Ontario Pharmacists Association strongly recommends that any such situations be documented, and we will be looking to create a mechanism to track these situations so that accurate feedback can be provided to the Ministry during ongoing discussions.

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30. If we will be dispensing monthly due to clinical reasons, what would be the intervention code to allow for this?

At this point in time, specifics around new intervention codes are not available. The Ministry has informed OPA that the mechanism to track the exemptions won't be in place until mid-2016. The Association is compiling a list of best practices to assist pharmacists in monitoring and tracking. However, we defer to any pre-set guidelines established by pharmacy owners, corporate head offices and/or pharmacy software vendors.

Regardless of the mechanism that a pharmacy will implement, OPA recommends that pharmacy team meetings/communiques be coordinated as soon as possible to ensure that all team members are is in sync with each other.

31. How does this impact the quantity of medications that we choose to renew with expanded scope? If we opt to renew only 30 days for a chronic medication to ensure patient follows up accordingly with their original prescriber, there is risk that they may run into the maximum 5 dispensing fee limit even faster.

Pursuant to our expanded scope of practice, pharmacists are enabled to offer prescription extensions where all refills have been exhausted for purposes of continuity of care. In the case of a chronic, stable medication that happens to be on the Ministry's list of 112 molecules, best practice would suggest an extension for the maximum amount allowed – that is, the amount last prescribed by the prescriber or the maximum allowable under the ODB program. This may not alleviate the situation completely, but it does help.

Further to this, the act of conducting a prescription extension is, like compliance packaging, an uninsured professional pharmacy service and requires a cognitive assessment by the pharmacist. Therefore, pharmacists are within their rights to charge a fair and reasonable professional fee – unattached to the dispensing fee – to the patient for the provision of this important service.

32. Some registered retirement homes administer meds to residents and need a pre-packaged system in order to give meds in a safe and timely fashion. In this instance does a form have to be filled out for every resident to allow for twice monthly dispensing of medications?

While there was significant discussion to this effect, it was felt that for the most part, seniors residing in retirement homes were best addressed in the same manner as those residing in their private homes. Furthermore, it was believed that the patient-based criteria that applies to the general ODB senior population would equally address the needs of those in retirement homes.

Therefore, the 5/365 rule applies for those residents in retirement homes, unless they meet the identified criteria, in which case OPA's documentation/consent/notification form would be used.

33. As in the case of existing 'no sub' prior to Oct 1st, which will be "grandfathered" in, can this be applied to existing documentation for compliance packaging? i.e., can documentation related to compliance be grandfathered ?

As of October 1, 2015, the documentation requirements set by the Ministry are clear in terms of specifics:

- Pharmacist's Decision – identify and provide the rationale for one of the identified impairments or to declare the presence of a complex medication regimen
- Patient/Agent Consent – this is required consent for more frequent dispensing, recognizing that if the patient qualifies, there will be a fee that will be passed on to the Ministry which that means the patient will see their copayment continuing with each transaction. (This is not an "either/or" situation - patient consent in the absence of one of the exception criteria is not sufficient; the patient must first be eligible and then must sign the document.
- Prescriber Notification – It is important to know that pharmacists possess full authority to make these decisions and will therefore be accountable for the veracity and authenticity of those decisions. The requirement is simply notification of the prescriber or prescribers, if there is more than one. There is no need whatsoever for prescriber authorization, permission or even response.

It has also been stated that the new documentation requirements will only be valid for 365 days. Therefore, grandparenting of documentation would not be approved.

Notwithstanding previous documentation efforts, OPA strongly recommends that pharmacists formally reassess their compliance package patients, that all affected patients (or their agents) reaffirm their consent, and that all relevant prescribers are notified once again. Finally, depending on the criteria on which you rely to make your clinical decision, you may need to regularly reassess the need for ongoing short-term dispensing throughout the 365-day period.

34. Can chronic medications which appear on the ODB list be packaged with psychiatric medications in a blister pack? This is for patient safety reasons.

The regulations pertaining to the frequency of dispensing have absolutely no bearing on how you prepare your blister packs. They only deal with how frequently dispensing fees associated with the meds within them get paid. How you want to package your patient's medications is entirely your decision and is in no way changed.

If you are packaging chronic meds and psychiatric meds together, you will simply need to coordinate the timing of billings of dispensing fees. Psychiatric meds will most likely fall on the Short Term Dispensing List (STDL) of 2008 and fees for these meds will be paid with each dispense with no limit. Conversely, chronic med dispensing fees will only be payable at a maximum frequency of twice per calendar month, but only if the patient meets the established criteria of an impairment (likely cognitive in this case) and/or "complex medication regimen".

Documentation requirements are no different than any other instance of more frequent dispensing.

35. Psychiatric patients are poor historians. What if they either don't provide information on previous Rx fills or simply can't remember? Can we defer to the prescriber?

Document as much information as you are able to, supplementing with information from the prescriber if warranted.

36. The Drug Profile Viewer (DPV) that has been used in hospital emergency rooms to provide clinicians with a snapshot of transactions submitted to ODB patients. This tool would be great source of Rx fill data and history for community pharmacy. Has this been considered?

OPA offered a strong recommendation for providing access for the DPV to all pharmacies to enable them to see their patient's ODB claims. This would have proven

very helpful in tracking chronic dispensing events and managing “No Sub” claims. Unfortunately, the Ministry indicated that while this would have been helpful, it is not at all possible in the short or even intermediate term.

The Ontario Pharmacists Association thanks those members who submitted questions in advance of/during the telephone town hall meetings. We acknowledge the challenges that members are anticipating when it comes to implementing these changes, and how the changes may impact workflow and the provision of an uninterrupted, consistent level of care for patients.

As always, OPA staff are available to members to answer questions and to provide guidance and information as needed. Members are invited to submit questions, comments and ongoing feedback to info@opatoday.com. The Association will try to post questions and answers to our website which we believe will support all members in implementing these changes.