Review of

PharmaCare Special Authority

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INTERNAL AUDIT
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Review of PharmaCare Special Authority

Internal Audit & Advisory Services
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Executive Summary

The Special Authority unit is part of the Pharmaceutical Services Division in the Ministry of Health (the Ministry) and supports cost-effective patient access to appropriate treatments. The unit grants full benefit status to a drug, medical supply or device that would otherwise not be covered or only partially covered under the PharmaCare program through manual staff approval and pre-approval processes. Eligibility for full benefit status is given to patients who meet pre-defined criteria for coverage. As a percentage of total PharmaCare spending, the portion relating to special authority grew from 39% to 53% over the past five years.

Special Authority Mandate

Granting special authority is enabled by the *Pharmaceutical Services Act* (the *Act)* and PharmaCare policies. The Special Authority unit acts on behalf of the Minister of Health in authorizing these special payments under the *Act* and helps ensure coverage is granted for eligible patients.

Performance measurement related to the Special Authority unit is limited. Current indicators focus on the number of requests completed but do not consider all categories of special authorities granted, nor do they illustrate how the unit contributes to achieving ministry objectives.

Formulary Management

The Formulary Management unit is responsible for overseeing the provincial drug review process which determines whether drugs should be added to the list of drugs covered by PharmaCare. The drug review process has three stages: Health Canada, National Common Drug Review, and BC Drug Benefit Council. Following this process, staff from the Special Authority and Formulary Management units make final drug coverage decisions about whether drugs should receive regular, partial, or limited benefit coverage.

Over the past five years, nearly three quarters of the new drugs being covered by PharmaCare are covered as partial benefit or limited coverage. This increases the demand on the Special Authority unit.

Formulary Optimization

In 2010, the Ministry reviewed the status of 19 drugs and assessed whether changing them from partial benefit or limited coverage to full benefit would reduce workload without significantly impacting provincial expenditures. The assessment resulted in one drug being given full benefit status and five others being recommended as candidates for pre-approval. Periodic reviews of drug benefit status would help ensure ministry decisions reflect current information on clinical efficacy, safety, and cost-effectiveness.

Staff-Approved Special Authority

The process to receive, file, and adjudicate faxed requests is manual and supported by clearly defined roles and responsibilities, procedures, and technical guides. Each request is usually handled by at least two staff before a decision is made and communicated back to the initiating prescriber. Typically, this process can be completed in less than ten minutes, as staff become adept at recognizing acceptance criteria through the repetitive nature of the work.

Requests received by telephone are immediately processed and can be advantageous as staff obtain all required information to support the request, reducing the incidence of missing information or duplication. However, the lack of clear protocols for telephone requests can result in non-urgent telephone requests being handled before other, more urgent, faxed requests. The telephone channel could be optimized by identifying which requests are best suited to this form of communication. For example, diverting requests that typically require immediate attention or are often missing information could maximize the benefits of this channel.

Given the high volume, low complexity and repetitive nature of this process, staff-approved special authority would be well suited for increased automation.

Duplicate or Incomplete Requests

In 2017, duplicate and incomplete requests comprised nearly 31% of the total workload for regular staff-approved special authority. Managing requests received with insufficient information requires additional time and effort, with back and forth communication between staff and prescribers. Processing duplicate requests and addressing those with missing information unnecessarily increases workload and ultimately impacts the timeliness for patients to receive a coverage decision.

Turnaround Times

To help facilitate timely patient care, requests are triaged as urgent, priority, or regular. Actual achievement rates show that planned turnaround times are infrequently achieved for regular, and seldom for priority. Publicly linking realistic turnaround times to actual results and specific medications, or classes of medications, would provide prescribers with a clearer understanding of when to expect a response. This would result in increased transparency, accountability, and may also help reduce duplicate requests or telephone inquiries on the status of requests.

Committee-Approved

Some special authority drugs are more expensive, involve more complex treatments and warrant greater scrutiny. Requests to receive coverage for these drugs are reviewed by one of six committees which involve contracted medical professionals who specialize in specific therapeutic areas. These committees provide case-by-case adjudication, advice and decisions. Although the drugs adjudicated through committees represented less than 20% of manual requests in 2017, they amounted to over 50% of all PharmaCare Special Authority expenditures.

Requests that go to committee are more resource-intensive to adjudicate as staff compile required information, either from the prescriber or through internal databases, to adjudicate the request. This additional documentation enables a more rigorous scrutiny of clinical evidence which supports the decision to approve or reject. Given the higher cost and complexity of these drugs, this stream provides an important level of validation and scrutiny over the applications and is less suitable for automation.

Pre-Approved Special Authority

The Special Authority unit has two categories of pre-approved special authority: prescriber exemptions and Collaborative Prescribing Agreements. Of the approximately 328,000 pre-approved special authorities in 2017, 92% were prescriber exemptions with the remaining 8% being Collaborative Prescribing Agreements. Neither of these categories requires a specific request for a special authority to be granted offering time-saving and efficiency benefits although potentially increasing the risk that more cost-effective therapies have not been used.

Roles and responsibilities over the pre-approved special authorities are not clearly defined. Doing so would establish accountability and provide greater clarity on ministry expectations regarding prescribing criteria for pre-approved special authority.

Prescriber exemptions predate the *Act* and were established on the premise that patients seeing certain specialists would generally satisfy the clinical criteria to receive Special Authority. There are no written agreements with prescriber exemptions where physicians agree to prescribing criteria, such as using more cost-effective first line therapies, before prescribing a special authority drug. A limited sampling indicated varying rates of adherence to prescribing criteria.

Collaborative Prescribing Agreements began in 2010 and have generally replaced prescriber exemptions as the pre-approved special authority method. These agreements include monitoring and accountability clauses with defined prescribing criteria. Regular reviews of how agreements are performing would enable the Ministry to assess their continued effectiveness and help the unit demonstrate its accountability over these agreements.

Quality Assurance

An effective quality assurance program involves continuous and systematic risk-based evaluation of activities to ensure they are meeting expectations. Currently, staff resources are primarily deployed in the manual special authority stream and there is no quality assurance on pre-approved prescriber exemptions. A strategic risk-based approach to quality assurance would produce an effective way of sampling high-risk or high-cost requests for appropriateness.

Technology

The Special Authority unit currently uses a number of legacy IT applications and internally developed aids to help staff maximize the efficiency of their workflow. However, these are not integrated requiring staff to access multiple applications to adjudicate requests. In addition, the unit's current technology has limited business intelligence capabilities, impeding its ability to efficiently analyze its existing data. A recently prepared "Electronic/Integrated Special Authority" project charter proposes to enable requests to be electronically submitted with automated adjudication for selected drugs.

Technological assessments of fax capability completed to date have not specifically assessed whether existing lines were sufficient for current and expected demand. A review of December 2017 fax data found that fax capacity was sufficient. However, with expected increases in fax volumes, the Special Authority unit should periodically review its fax capacity to minimize the potential of fax failures.

User Access & Information Management

Special Authority requests contain personal information. Given the confidential nature of this information, it is important that access is managed appropriately and securely. Implementing additional controls that ensure information is retained in a secure environment, including one that limits access to files, would provide greater security over patient information.

Having controls to restrict and manage user access to critical applications is essential in protecting Ministry information. The Special Authority unit grants staff access to applications commensurate with their job functions. A recent review identified user accounts that no longer needed access due to moving ministries or leaving government and existing staff with unnecessary access. Periodically reviewing user access helps ensure only authorized users access the information needed to perform their job duties.

Future IT and Data Capabilities

The Electronic/Integrated Special Authority project charter, and supporting documentation, outlines desired technology enhancements to improve the efficiency of delivering pharmaceutical drugs and selected medical supplies. In addition to the enhancements outlined in the charter, there are other capabilities that would be beneficial when considering improvements to its current business processes.

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We would like to thank the management and staff of the Ministry of Health, in particular within the Special Authority and Formulary Management units who participated in and contributed to this review for their cooperation and assistance.

Stephen A. Ward, CPA, CA, CIA
Executive Director
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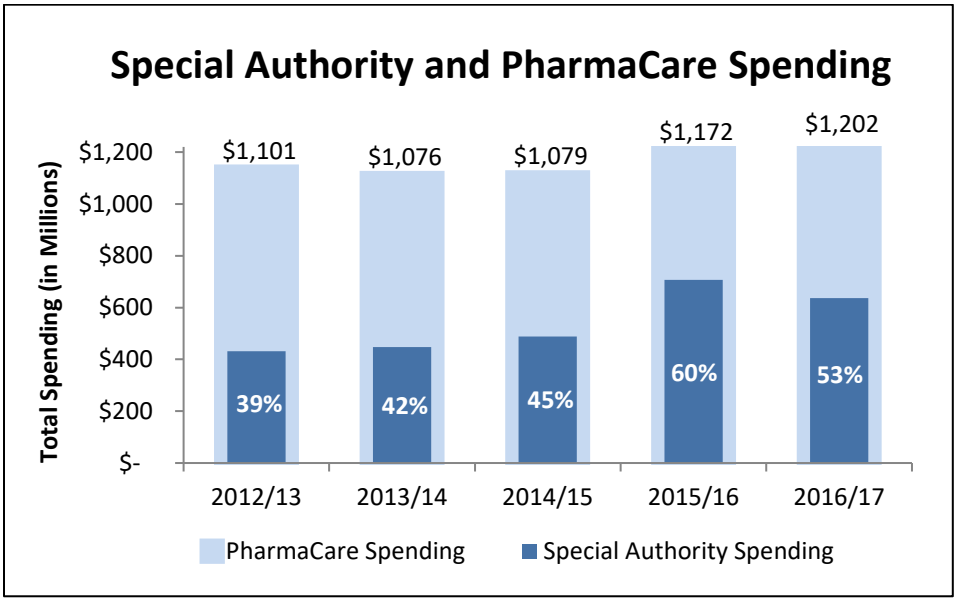
Ministry of Finance

Introduction

The BC PharmaCare program covers the cost of eligible prescription drugs and medical supplies for British Columbians through several drug plans. PharmaCare does not cover all prescription drugs; it covers drugs based on their effectiveness and cost.

BC PharmaCare's Special Authority unit, part of the Pharmaceutical Services Division, is mandated to deliver cost-effective PharmaCare coverage while ensuring patients get access to appropriate treatments. Once approved, a special authority grants full benefit status to a drug, medical supply or device that would otherwise not be covered or only partially covered under the PharmaCare program. Eligibility for full benefit status is given to patients who meet pre-defined criteria for coverage.

As illustrated below, the special authority percentage of total PharmaCare spending grew from 39% to 53% over the past five years.



Source: Ministry of Health

For patients who need coverage for a drug that might otherwise not be fully covered, their health care provider submits a special authority request for coverage. Currently, the process for adjudicating fax or telephone requests is largely manual with many steps and requiring a substantial portion of staff time. In 2017, over 208,000 requests were processed manually, representing 39% of the special authorities granted.

Specific groups of medical specialists are pre-approved to prescribe certain limited coverage drugs and receive full benefit status without submitting requests. In 2017, over 320,000 requests were pre-approved.

Through various LEAN and continuous improvement initiatives, the process of adjudicating manual workflows has been extensively reviewed. Impediments to efficiency persist despite these efforts. While additional enhancements can streamline bottlenecks, this can only be done to the extent that technology allows. Recently, an Electronic/Integrated Special Authority project was proposed to the Ministry's executive project committee that offers solutions to many of the current impediments faced by the unit.

Purpose, Scope and Approach

The purpose of this review was to examine the PharmaCare Special Authority program to identify potential efficiencies and cost-benefit improvements.

The scope of this review focused on the process, policies and technology used by the Special Authority unit. The review evaluated and, as appropriate, made recommendations to the following:

- The efficiency of Special Authority practices, including review, adjudication and approval of requests.
- Formulary management practices with a specific focus on identifying cost-benefit opportunities for the Special Authority unit.
- Key information technology capabilities required for Special Authority including the assessment of risks related with the current technology, and the Electronic/Integrated Special Authority project planning.

Special Authority resulting from policy changes applying to large subsets of the population were excluded from this review.

Our approach included a review of the Special Authority unit's request processing practices, policies, and information technology. The approach included:

- Reviewing policy documents and interviewing ministry staff involved in those processes.
- Judgemental sampling and analyzing data developed by the Ministry.
- Identifying the similarities and differences of Special Authority processes in other jurisdictions.

The review, requested by the Ministry of Health (the Ministry), was conducted by Internal Audit and Advisory Services, Ministry of Finance.

Overall Conclusion

The Special Authority unit is responsible for authorizing patient-specific PharmaCare benefits for drugs that are not fully covered. The Special Authority unit acts on behalf of the Minister of Health in providing special authority coverage under the *Pharmaceutical Services Act*. There are currently two types of approvals for special authority: manually prepared and approved requests and pre-approvals where a special authority prescription is issued without submitting a request.

Manually prepared requests receive varying degrees of scrutiny. Adjudicating most requests involves verifying that approval conditions have been listed on the request. Case-by-case verification over the validity of assertions made on the request is performed for the most expensive categories of drugs, representing about half of all special authority expenditures. Through these processes, the Special Authority unit increases their assurance that a cost-effective approach to prescribing is being followed.

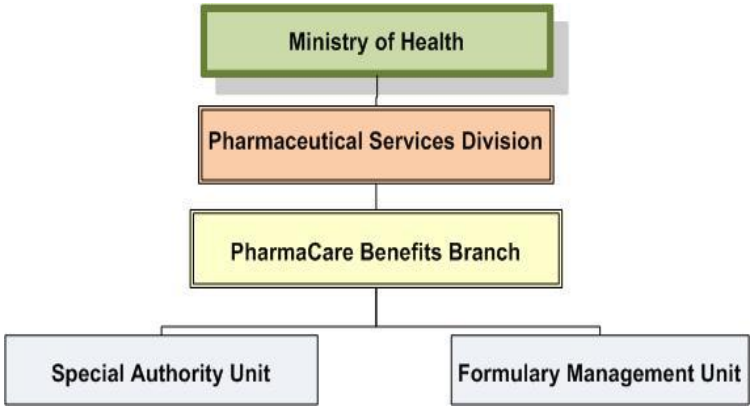
Pre-approved special authorities were created for prescribers whose patients generally meet the conditions required for approval. With pre-approved authorizations, there is no regular scrutiny to establish how consistently the prescribing guidelines are being met.

The Special Authority unit should reassess how it monitors and oversees approvals using a risk-based approach covering both staff-approved and pre-approved streams. This would also help define performance measures that would demonstrate how the unit delivers on its mandate.

The Special Authority unit has made efforts to streamline their current processes to the extent available with existing technology. Opportunities remain for further incremental enhancements and reducing known challenges, such as duplicate requests. A proposed Electronic/Integrated Special Authority project presents an opportunity to enhance the efficiency, timeliness, and transparency of the adjudication process and could provide meaningful business intelligence to inform the units' activities.

1.0 Special Authority

The PharmaCare Benefits Branch within the Ministry of Health has responsibility over the Formulary Management and Special Authority units as follows:



The Formulary Management unit manages the array of drugs eligible for reimbursement through the provincial PharmaCare Plans. Drug coverage is determined based on drug benefit decisions made through the formulary management process. The Special Authority unit manages the program that grants full benefit for limited coverage drugs based on pre-established criteria.

What is a Formulary?

In BC, the Formulary is the list of drugs covered by PharmaCare

Over the past five years, the Special Authority unit grew from 29 staff to 40 (38%) with a corresponding 28% growth in requests for Special Authority, many with increasing complexity.

1.1 Special Authority Mandate

The Special Authority unit is responsible for authorizing patient-specific PharmaCare coverage, under certain conditions, for drugs that are not fully covered. Special Authority is enabled by the *Pharmaceutical Services Act* (the *Act*) and PharmaCare policies. The Special Authority unit acts on behalf of the Minister of Health in providing these special payments under the *Act*.

In managing patients-specific requests, the unit delivers its mandate by helping ensure appropriate coverage is granted for eligible patients. There are varying degrees of scrutiny provided over the different avenues for granting special authority. Although in part a risk-based approach where more expensive and complex drugs receive greater scrutiny is being used, more work is needed to rationalize the approach in the other areas.

Ensuring value for money in health care was a key goal in the Ministry's 2017/18 – 2019/20 Service Plan, though it has since been replaced in the Ministry's most recent Plan. A strategy to help achieve this goal included providing "evidence-informed access to clinically effective and cost-effective pharmaceuticals". The 2016/17 Branch Plan incorporates this Ministry goal into its objectives although it does not include performance indicators or targets for the Special Authority unit to measure and demonstrate its success in meeting its and the Ministry's objectives.

Performance measurement related to the Special Authority unit is currently limited to measuring the workload of requests received and processed. This indicator focuses on manually-processed requests but does not consider all categories of special authorities granted nor does it illustrate how the unit contributes to ensuring their work is helping delivering cost-effective pharmaceuticals.

Recommendation:

(1) The Special Authority unit should identify performance measures and report on its performance in delivering cost-effective pharmaceuticals.

1.2 Formulary Management

The Formulary Management unit, within the PharmaCare Benefits Branch, is primarily responsible for overseeing the provincial drug review process which determines whether drugs should be added to the formulary.

Drug Review Process

The drug review process has three stages. As outlined in the visual below, there are two national-level reviews followed by a provincial review:

Once a Drug Benefit Council recommendation is made, and pricing is optimized through pan-Canadian Pharmaceutical Alliance negotiation, the Ministry makes a final drug coverage decision.

Drug Benefit Status

The Ministry assigns a benefit status of full, partial, or limited coverage.

- **Regular benefit drugs:** are eligible for full PharmaCare coverage, subject to the individual's plan.
- **Partial benefit drugs**: are covered up to a specific price limit under the Low Cost Alternative Program or Reference Drug Program. A patient may obtain full benefit coverage of a partial benefit drug through Special Authority.
- **Limited coverage drugs**: are drugs for which a more cost-effective alternative exists and therefore are not normally regarded as first line therapies. A patient may obtain full benefit coverage of a limited coverage drug through Special Authority.

Over the past five years, nearly three quarters of the drugs added to the formulary have been listed as partial benefit or limited coverage, increasing demand for Special Authority. In weighing the benefits and costs of limiting coverage for new drugs, the Ministry's budget assessments have typically concluded that adding staff to meet increased demand is more cost-effective than making the drug full benefit.

Formulary Optimization

The Formulary Management unit manages the drug review process and the status of drugs within the formulary. Once drugs are in the formulary, there is no review mechanism to determine whether changing their status would create cost-benefit opportunities.

In 2010, the Ministry conducted a review to assess whether changing the status of 19 drugs from partial benefit or limited coverage to full benefit would reduce workload without significantly impacting provincial expenditures. The review resulted in one drug being given full benefit status, with five others being recommended as candidates for preapproval.

Periodic reviews of drug benefit status would help ensure ministry decisions continue to reflect current information on clinical efficacy, safety, and cost-effectiveness.

Recommendation:

(2) The Ministry should periodically review the drugs in the formulary to ensure their benefit status remains appropriate.

1.3 Provincial Comparisons

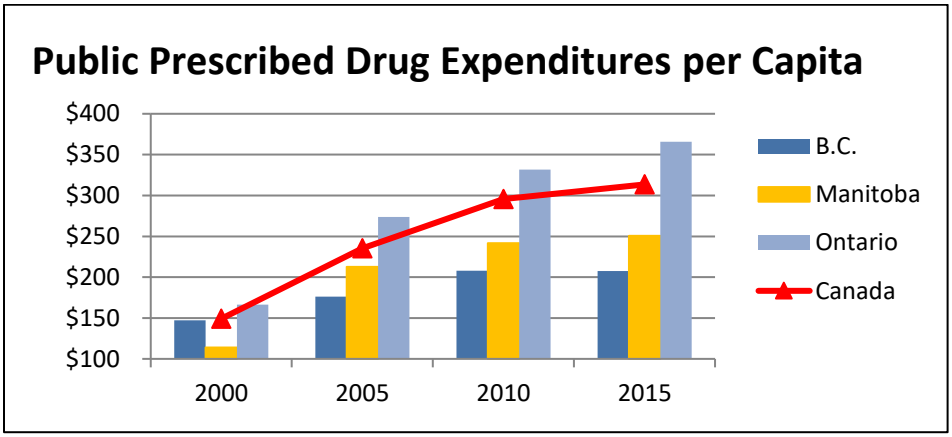
The provision of patient-specific access to limited coverage drugs varies among the provinces. Alberta and Nova Scotia delegate special authority adjudication to a third party service provider, whereas Ontario and Manitoba have a similar process to British Columbia (BC). Based on the similarities, in size and nature to BC, these two provinces were identified as suitable comparators.

BC has a significantly higher volume of Special Authority requests compared to Ontario and Manitoba. In 2017, BC received approximately 208,000 requests compared to 90,000 for Ontario and 60,000 for Manitoba. While BC and Ontario accept telephone calls, which are processed in "real-time", Manitoba phased this out in 2017.

Ontario and Manitoba have similar challenges in processing requests as observed in BC, including a growing volume of requests with increasing complexity, incomplete and duplicate applications, and staff turnover. Ontario is in the process of implementing an electronic system to address many of these problems.

Each province takes measures to reduce their workload. For example, BC and Ontario allow certain limited coverage drugs to be prescribed without submitting applications. Manitoba does not require renewals after the initial special authority is approved.

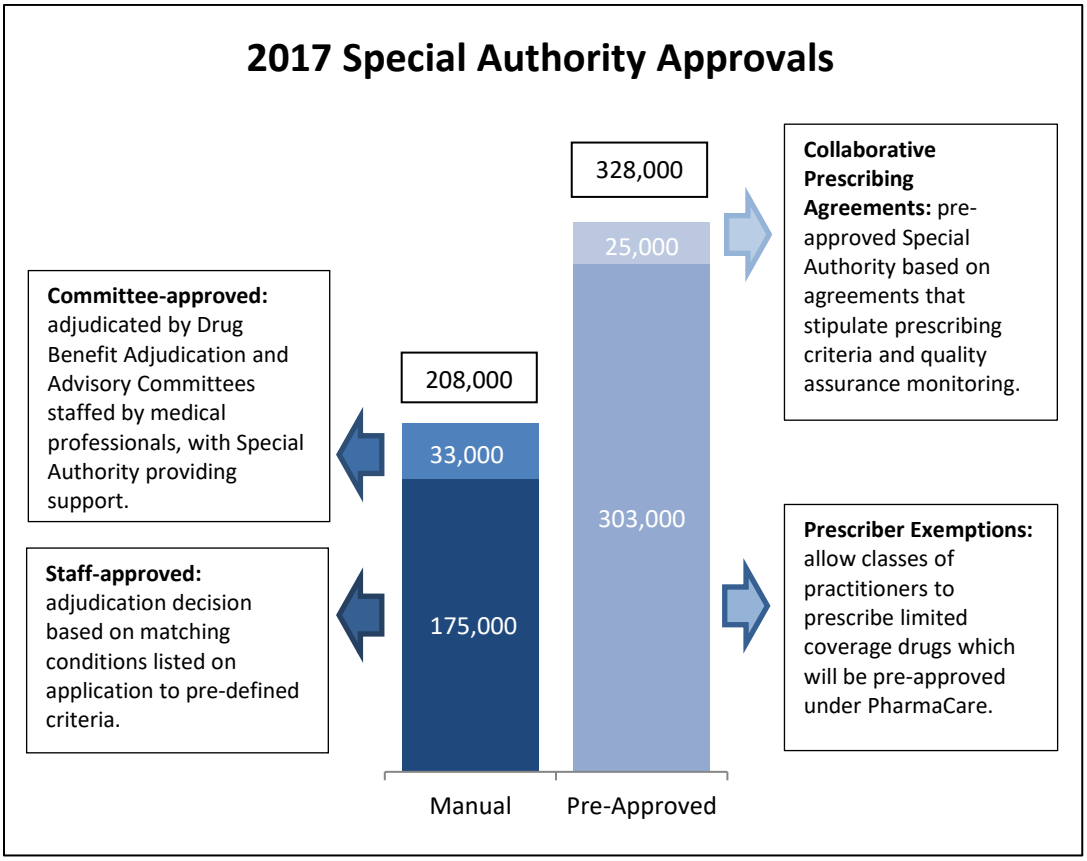
The Canadian Institute for Health Information publishes data relating to Canadian health care. According to this data, and as illustrated below, BC had the lowest public prescribed drug expenditure growth per capita from 2000 to 2015 which suggests it has effectively limited public prescribed drug expenditures over this period.



Source: Canadian Institute for Health Information

2.0 Processing Workflows

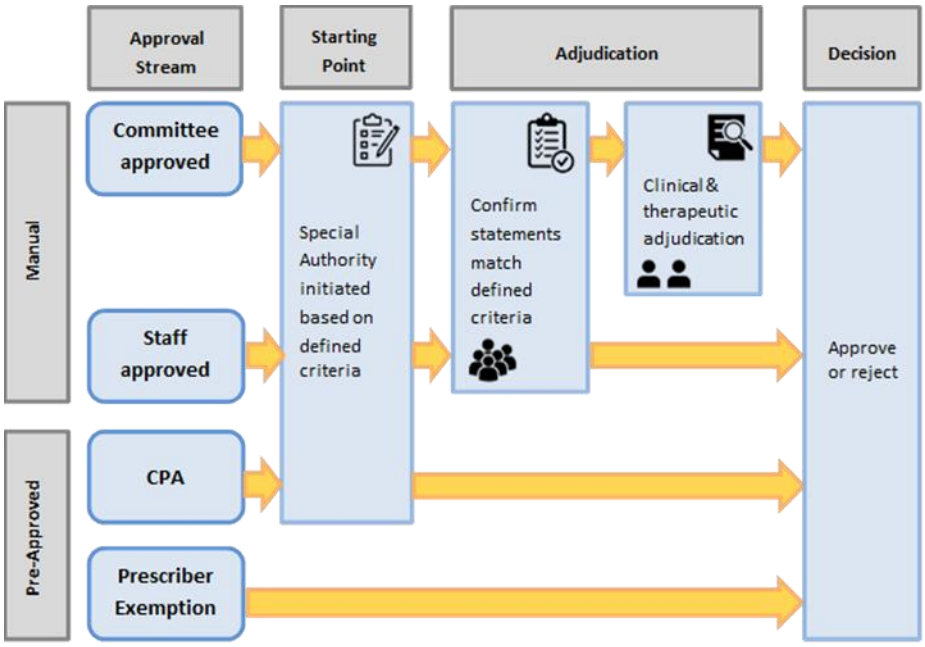
Special Authority is granted through a manual approval process or pre-approved when prescribers, such as a family doctor or specialist, have exemptions or agreements in place.



Source: Ministry of Health

The above chart shows the volume of special authority approvals in 2017 through each process. The various special authority approvals, such as staff and committee approved, or prescriber exemptions and collaborative prescribing agreements, are defined.

As illustrated in the following chart, manual and pre-approved special authorities have different approval streams with varying degrees of adjudication before the decision to approve or reject.



Source: IAAS adapted from Special Authority Unit

The unit's resources are devoted primarily to processing manual staff-approved requests. With pre-approved authorizations, there is no regular scrutiny to establish how consistently prescribing guidelines are followed.

2.1 Manual Special Authority

The volume of manual requests has been consistently increasing over time as a result of new medications being added to the formulary with limited coverage conditions and more complex criteria. In October 2017, the First Nations Health Authority transitioned to PharmaCare resulting in a further 10% increase in fax and telephone call volumes from October through December compared to the previous months of 2017. Within this stream the unit has performed numerous LEAN and continuous improvement exercises.

Staff-Approved Special Authority

When a request is received by fax, a software application converts it into an image file and saves it to the Ministry network. These images are triaged by clerks based on priority and type before being adjudicated by technicians and pharmacists. Certain expensive or complex requests are adjudicated by Drug Benefit Adjudication and Advisory Committees (committees). Once coverage is approved, patient information is entered into PharmaNet, stored, and communicated to the requesting prescriber.

> What is PharmaNet?
>
> *A province-wide network that links all BC pharmacies to a central database.*

The process to receive, file, and adjudicate requests is largely manual and supported by clearly defined roles and responsibilities, procedures, and technical guides. Each request is usually handled by at least two staff before a decision is made and communicated back to the initiating prescriber.

Typically, this process can be completed in less than ten minutes. Most of the time involves “stamping” key phrases to the imaged fax file though the adjudication decision itself can be very fast as staff become adept at recognizing criteria through the repetitive nature of the work. Information provided on these applications is usually taken as stated, making the decision a matter of ensuring that appropriate criteria are listed for approval. Given the high volume, low complexity and repetitive nature of this process, staff-approved special authority would be well suited for increased automation.

Requests received by telephone are immediately processed. In December 2017, over 1,700 telephone calls were received. Approximately 40% of these calls were for a request, of which less than half were urgent. The remainder of the calls were to either check on the status of an application or for other reasons not categorized.

Telephone requests have advantages as staff can ensure all required information is gathered to support the request, reducing the incidence of missing information or duplication. However, the lack of clear protocol for telephone requests can result in non-urgent telephone requests being handled before other, more urgent, faxed requests.

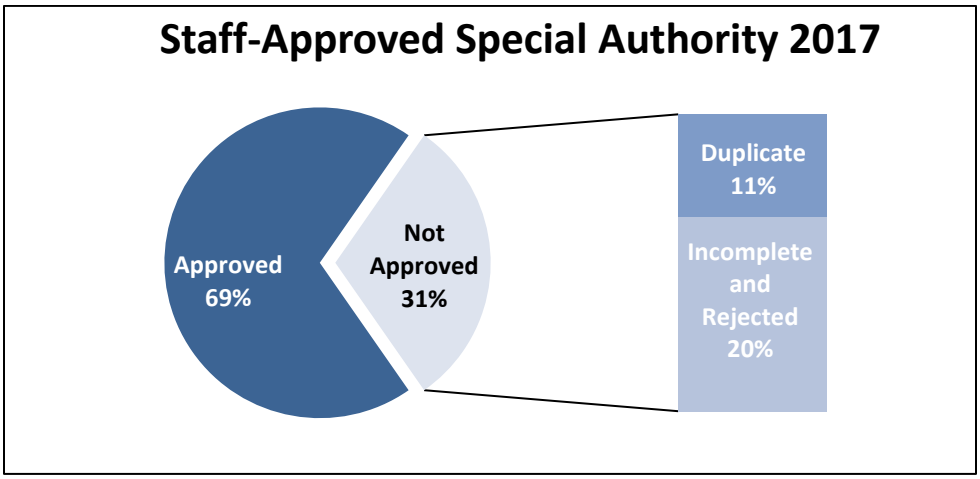
The telephone channel could be optimized by identifying which requests are best suited to this form of communication. For example, diverting requests that require immediate attention or are often missing information could maximize the benefits of this channel.

Recommendation:

(3) The Special Authority unit should optimize the telephone channel to ensure it appropriately prioritizes patient needs.

Duplicate or Incomplete Requests

In 2017, duplicate and incomplete requests comprised nearly 31% of the total workload for regular staff-approved special authority, as illustrated below:



Source: Special Authority Unit

Managing requests that contain insufficient information requires additional staff time and effort. These requests are rejected and faxed back to the prescriber indicating what information is required to properly complete the request. Missing information can include omitting the correct clinical criteria and prescriber or patient information. These requests are then revised by the prescriber to include the missing information and sent back.

Duplicate requests can result from confusion where prescribers are unclear whether their initial request has been received. Duplicates are only identified after they are reviewed and approved by staff and would be entered into PharmaNet. These consume a similar amount of time to process and are returned to the prescribers with a notation that the request is a duplicate and the medication has already been approved.

A review of 2017 requests identified the most extreme example having 12 separate requests associated with one approved Special Authority. Although this example is the worst case identified, there were many similar instances of multiple requests relating to one approval. Processing duplicate requests and addressing those with missing information unnecessarily increases workload and ultimately impacts the timeliness for patients to receive a coverage decision.

Turnaround Times

To help facilitate timely patient care, requests are triaged as they are received and sorted into one of three categories:

- **Urgent:** drugs to treat life-threatening situations, or if indicated by the prescriber.
- **Priority:** drugs not seen as urgent, but by their nature would require a relatively quick turnaround.
- **Regular:** drugs not deemed as urgent or priority.

Estimated turnaround times should reflect when prescribers can reasonably expect a response. These estimates are published on the Ministry's website. While actual achievement rates are tracked internally, they are not published. As shown in the following table, achievement rates in 2017 for priority and regular requests suggest these estimated turnaround times are not realistic.

Request Type	Turnaround Time	Achievement Rate
Urgent	1 business day	100%
Priority	3 business days	8%
Regular	10 business days	58%

Source: Special Authority Unit

Clearly linking realistic turnaround times to actual results and specific medications, or classes of medications, would provide physicians with a clearer understanding of when to expect a response. This would result in increased transparency, accountability, and may also help reduce duplicate requests or telephone inquiries on the status of requests.

Recommendation:

(4) Estimated turnaround times should be realistic, clearly associated to specific medications, and actual achievement rates published.

Committee-Approved

Some special authority drugs are more expensive, involve more complex treatments and warrant greater scrutiny. Requests to receive coverage for these drugs are reviewed by one of six committees which involve contracted medical professionals who specialize in specific therapeutic areas.

These committees provide case-by-case adjudication, advice and decisions. Although the drugs adjudicated through committees represented less than 20% of manual requests in 2017, they amounted to over 50% of all PharmaCare Special Authority expenditures.

Requests that go to a committee are more resource-intensive to adjudicate. Staff support the committees by compiling information needed, either from the prescriber or through internal databases, to adjudicate the request. This additional documentation enables a more rigorous scrutiny of clinical evidence which supports the decision to approve or reject.

Given the higher cost and complexity of these drugs, this stream provides an important level of validation and scrutiny over the applications and would not be as suited to automation.

2.2 Pre-Approved Special Authority

The Special Authority unit has two categories of pre-approved special authority: prescriber exemptions and Collaborative Prescribing Agreements (CPA's). Neither of these categories requires a specific request for a special authority to be granted.

Of the approximately 328,000 pre-approved special authorities in 2017, 92% were prescriber exemptions with the remaining 8% being CPAs. These have a significant advantage in time-saving and efficiency. However, pre-approved channels may also increase the risk that more cost-effective therapies have not been used.

Roles and responsibilities over pre-approved special authorities are not clearly defined. For example, no staff are currently assigned any responsibility over prescriber exemptions and CPA reporting is done on an ad-hoc basis, when time permits. Assigning roles and responsibilities would establish accountability and provide greater clarity on ministry expectations regarding prescribing criteria for pre-approved special authority.

Prescriber Exemptions

Prescriber exemptions predate the *Act* and were established on the premise that patients seeing certain specialists would generally satisfy the clinical criteria to receive Special Authority. These exemptions provide benefits by reducing the administrative workload on prescribers and lowering the volume of manual requests. Generally, special authority drugs prescribed by this category of physician are to treat specific conditions under a specialty area. For example:

- psychiatrists have exemptions for drugs to treat depression;
- respirologists have exemptions for drugs to treat asthma; and
- oncologists have exemptions for drugs that support cancer treatment.

There are no written agreements with prescriber exemptions where physicians agree to prescribing criteria, such as using more cost-effective first line therapies, before prescribing a special authority drug. As well, there are no staff assigned to scrutinize the prescribing practices occurring within this workflow. The absence of agreements combined with lack of oversight, restricts the Ministry's ability to fulfill its accountability over these exemptions.

An internal assessment completed in 2015 of one prescriber exemption identified that more cost-effective products in the class were often not trialed prior to the Special Authority prescription being issued. The result was to remove this exemption. Also, a sample of three categories of limited coverage drugs determined a range of adherence to expected prescribing criteria of 55% to 97%. In categories where the compliance is below a defined threshold, there is opportunity for the Special Authority unit to better understand the reasons and take steps to improve compliance.

These results highlight the need for additional monitoring and oversight over pre-approved special authority drugs in helping the unit demonstrate their accountability over cost-effective prescribing patterns. The ministry recognizes the limitations in its current practices and has committed to taking action in these areas.

Collaborative Prescribing Agreements

Collaborative Prescribing Agreements began in 2010. Agreements include monitoring and accountability clauses with defined prescribing criteria. These agreements have generally replaced prescriber exemptions as the pre-approved special authority method.

A recent internal report assessing whether CPA drugs were being prescribed according to the agreements, demonstrated cost-effectiveness, and were in demand by patients. The assessment resulted in one being discontinued with a number of others being recommended for continued investigation and monitoring. Regular reviews assessing CPA's would ensure agreements are beneficially structured, and risks are appropriately monitored. This would also enable the Ministry to assess their continued effectiveness and help the unit demonstrate its accountability over these agreements.

Recommendation:

(5) Roles and responsibilities over pre-approved special authority should be clearly defined.

2.3 Quality Assurance

An effective quality assurance program involves continuous and systematic risk-based evaluation of activities to ensure they are meeting expectations. Quality assurance varies by type of approval stream. Currently, staff resources are primarily deployed in the manual special authority stream. Currently, there is no quality assurance on pre-approved prescriber exemptions.

Quality assurance practices over staff-approved special authority requests focus on ensuring adjudication accuracy. This is typically completed through monthly sampling to confirm whether requests were appropriately adjudicated and information was correctly entered into PharmaNet. Where necessary, these results are used to inform staff training needs. This measure is appropriate given the manual nature of processing and the reliance on accurate data entry.

The Special Authority unit should have an understanding in all categories of special authority approvals about the degree of compliance with prescribing criteria. While the available technology limits these efforts, there are tests that can be conducted to enable stronger quality assurance practices, increasing the unit's accountability over all special authority approvals granted.

There is opportunity for the Special Authority unit to reassess how it monitors and oversees approvals using a risk-based approach covering both staff-approved and pre-approved streams. A similar approach to quality assurance would produce an effective way of identifying high-risk or high-cost requests for appropriateness.

Recommendation:

(6) The Special Authority unit should establish a risk-based approach for monitoring, oversight, and quality assurance over all special authority approvals.

3.0 Technology

It is important for an organization to have a technology that allows staff to complete their work efficiently and cost-effectively. Due to the Special Authority unit's work being time sensitive and highly repetitive as well as its confidential nature, technology is a key component to the unit.

The Special Authority unit currently uses a number of legacy IT applications and internally developed aids to help staff maximize the efficiency of their workflow. However, they are not integrated, requiring staff to access multiple IT applications to adjudicate some requests. In addition, the unit's current IT applications have limited business intelligence capabilities, thereby impeding their ability to efficiently analyze existing data.

In 2017, the unit submitted a proposal for an automated special authority system. If approved, this system intends to enable electronic capture of requests, automation, and enhanced business intelligence.

3.1 Current IT Capabilities and Risks

The Special Authority unit currently employs the following IT applications to assist its manual workflows:

- **LANFax:** A tool managed by a third party provider and used by the Special Authority unit to route incoming and outgoing faxes. Incoming faxes are converted to an image file and stored on the Ministry's local area network.

- **PharmaNet:** The province-wide drug system is managed by Health Insurance BC and utilized by the Ministry, BC pharmacies, and hospitals. The Special Authority unit uses PharmaNet to input information from approved requests and to search previous use of Special Authority coverage drugs. Typically patient prescription history is available for 18 months.

- **HealthIdeas:** An internal data warehouse used by the Ministry to store and secure BC resident's personal health information. The Special Authority unit accesses this data warehouse to research patient health and prescription history beyond 18 months to help inform decisions when adjudicating requests.

Although the current IT applications are limited in their functionality and are not integrated, there are opportunities to help utilize their full potential. For example, LANFax can be configured to:

- populate the prescribers' fax number on the fax image to act as a visual check for clerks to confirm consistency with the number listed on the Special Authority request, reducing the risk of returning a fax to an incorrect recipient; and

- modify the incoming fax's unique identifier to include the fax number of the prescriber submitting the request, to assist the Special Authority unit in identifying potential duplicates.

Implementing existing unused capabilities can improve the efficiency and cost-effectiveness of the Special Authority unit's business processes. By ensuring existing capabilities are maximized, the Special Authority unit may identify efficiencies when developing a new IT application.

Current Fax Capacity

The LANFax application currently has a 16 line capacity for incoming and outgoing faxes. However, technological assessments completed to date have not specifically assessed whether existing fax lines are sufficient for current demand or the growth projections.

As part of this review, December 2017 data determined that there were no more than 12 simultaneous incoming or outgoing faxes at any given time during the month. This suggests that there is sufficient capacity within the existing application. Periodic review to ensure fax capacity remains sufficient would minimize the potential of fax failures.

Information Management

The Province's Information Management practices help ensure the integrity, reliability, and accessibility of government records as well as records containing personal information of British Columbians. Special Authority requests contain details that include the patient's name, personal health number, date of birth, medication requested, and diagnosis.

Given the confidential and personal nature of information held by the Special Authority unit, it is important that access to this data is managed appropriately and secured from unauthorized access. All information retained by the unit is stored on an internal network. Implementing additional controls that ensure information is retained in a secure environment, including one that limits access to files, would provide greater security over patient information.

User Access and Identity Management

Having controls to restrict and manage users' access to critical applications is essential to protect ministry information. The Special Authority unit grants user access on the LANFax, HealthIdeas, and PharmaNet applications, commensurate to staffs' job functions.

Health Insurance BC staff also access PharmaNet and the Ministry's internal network folders in order to assist the Special Authority unit on phone calls related to status requests and, in limited cases, processing requests. Health Insurance BC staff have the same level of access to PharmaNet and the Ministry folders as Special Authority unit staff.

The Special Authority unit completed a PharmaNet user access review in February 2018. This review identified user accounts that no longer needed access due to moving ministries or leaving the BC Government and existing Special Authority unit staff with unnecessary access. The user access review identified that none of the users who moved ministries or left the BC Government had accessed PharmaNet since leaving the Ministry.

Periodically reviewing users' access helps ensure only appropriate users have access to the system. The BC Government Information Security Policy requires ministries to "periodically review access rights with the owners of the information systems or services". The Ministry's network security guide advises business units "should periodically review access to their network drives to ensure that access is appropriate".

The Special Authority unit currently does not have a regular process to review user access for PharmaNet and internal network folders, including from Health Insurance BC users.

Recommendation:

(7) The Special Authority unit should ensure information is securely retained and user accesses regularly reviewed.

Business Intelligence

Strong business intelligence is an integral part of a cost-effective, performance-based approach to delivering effective program oversight and services. The Special Authority unit has limited business intelligence to guide the focus of its activities. Currently, most internally-developed business intelligence is compiled by manual or system counts of requests. This information is then documented on a spreadsheet which is used for internal management purposes.

There is room to strengthen use of existing business intelligence using information currently available. For example, data can be extracted that can, in limited cases, establish whether first-line therapies were prescribed prior to special authority drugs. At an aggregate level, this indicator can help identify where additional awareness surrounding expected prescribing patterns is warranted.

Improving the Special Authority unit's ability to record and track pertinent data from application requests would provide key business intelligence for both the unit and across the Ministry. For example, improved business intelligence could:

- provide a better understanding of drug efficacy;
- provide comprehensive volume and drug utilization statistics; and
- generate a range of exception reports that allow for targeted quality assurance to be conducted.

3.2 Future IT and Data Capabilities

In 2017, the Special Authority unit prepared an Electronic/Integrated Special Authority project charter for approval to proceed to planning. A key component in this planning is developing a business case to assess the costs and benefits of various options.

This charter proposes to enable electronic capture and submission of Special Authority requests and automate the adjudication workflow for selected drugs with straight forward criteria. The proposed system includes the following benefits:

- enabling the submission of online application requests by prescribers, negating the need for fax, phone, or mail applications; and

- providing real-time adjudication and status updates to prescribers which would significantly reduce duplicate and rejected requests.

The extent of manual work involved in processing the increasing volume of requests, combined with opportunities to capture meaningful business intelligence, highlight the benefits that could be addressed through an electronic system. The potential to enhance business intelligence capabilities by capturing data flowing through the adjudication process offers additional key benefits. While automation may be appropriate for the highly repetitive workflows such as manual requests, the committee workflow involving more complex and expensive drugs is less suitable for automation.

The Electronic/Integrated Special Authority project charter, and supporting documentation, outlines desired technology enhancements to improve the efficiency of delivering pharmaceutical drugs and selected medical supplies. In addition to the enhancements outlined in the charter, there are other capabilities that would be beneficial when considering improvements to its current business processes. For example:

- Ensuring there is an audit trail when users are entering, adjudicating, and approving application requests to assist in monitoring workflows and improving the Special Authority unit's quality assurance process.

- Adding a business intelligence capability for the applications used by the unit. This would assist in gathering statistics and generating performance metrics on a range of drug utilization and prescription practices.

The Special Authority unit should ensure that they fully assess the functionality that would enable efficient workflows prior to implementing a new system.

Implementing a technology solution that provides real time adjudication or status updates would have the potential to eliminate many of the challenges discussed. For example, duplicate and rejected requests could be significantly reduced through online request submission and business intelligence enhanced through enabling stronger data collection capabilities. Meanwhile, existing resources could be redeployed to exercise greater scrutiny over pre-approved exemptions and assisting committee adjudication.

Recommendation:

(8) The Special Authority unit should develop a business case to assess costs and benefits of technological solutions.

Appendix 1 – Summary of Recommendations

1	The Special Authority unit should identify performance measures and report on its performance in delivering cost effective pharmaceuticals.
2	The Ministry should periodically review the drugs in the formulary to ensure their benefit status remains appropriate.
3	The Special Authority unit should optimize the telephone channel to ensure it appropriately prioritizes patient needs.
4	Estimated turnaround times should be realistic, clearly associated to specific medications, and actual achievement rates published.
5	Roles and responsibilities over pre-approved special authority should be clearly defined.
6	The Special Authority unit should establish a risk-based approach for monitoring, oversight, and quality assurance over all special authority approvals.
7	The Special Authority unit should ensure information is securely retained and user accesses regularly reviewed.
8	The Special Authority unit should develop a business case to assess costs and benefits of technological solutions.

Appendix 2 – Detailed Action Plan

Rec. #	Recommendations	Management Comments (Action Planned or Taken)	Target Date
1.	The Special Authority unit should identify performance measures and report on its performance in delivering cost effective pharmaceuticals.	1. Identify/reassess turnaround times 2. Therapeutics Initiative (TI) outcomes measures 3. Maintaining 95% plus accuracy rate 4. Develop a metric for identifying the number of back and forth requests and then set a goal to reduce it 5. Develop a metric to track and monitor the savings recognized through listing cost-effective new products	Establish Metrics: Oct. 2018 Report metrics: March 2019
2.	The Ministry should periodically review the drugs in the formulary to ensure their benefit status remains appropriate.	1. Hire new staff to address Optimal Use and Therapeutic Reviews for Ministry, working with the Therapeutics Initiative. Establish a process to systematically review and adjust the formulary (to be completed by Formulary Management, Therapeutic Review and Optimal Use teams as per new strategic direction for Division and contract with the Therapeutics Initiative) 2. Special Authority to continue to provide “medications of concern” to Pharmaceutical Services Strategic Implementation Team and Pharmaceutical Services Formulary Team through Special Authority Quality Assurance working group 3. Results of better stats tracking could be easier identification of problem areas	FY2018/19 Q4

The Detailed Action Plan represents the Special Authority unit’s response to the issues identified and the eight recommendations detailed in the 2018 report: *Review of PharmaCare Special Authority*. This document was prepared by the Special Authority unit and submitted to Internal Audit & Advisory Services to be included as an Appendix to the report.

Appendix 2 – Detailed Action Plan (continued)

Rec. #	Recommendations	Management Comments (Action Planned or Taken)	Target Date
3.	The Special Authority unit should optimize the telephone channel to ensure it appropriately prioritizes patient needs.	1. Triage incoming calls for committee medication requests 2. Stats to be evaluated monthly to identify requests best served by phone call 3. LEAN process reduced incoming calls/restructured phone tree 4. Based on data collected from Rec #1, develop optimization of phones	1. Completed 2. Oct. 2018 3. Completed 4. March 2019
4.	Estimated turnaround times should be realistic, clearly associated to specific medications, and actual achievement rates published.	1. Project team created 2. Re-evaluation of priority levels (and drugs for each) 3. Assess timelines for each priority level 4. Naming convention change 5. Plan to publish (need to connect with communications team) 6. Based on data collected from Rec #1, develop optimization of response timelines	Planning phase (1-3): Completed Implementation (4): Oct. 2018 Publish (5): Nov. 2018

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Appendix 2 – Detailed Action Plan (continued)

Rec. #	Recommendations	Management Comments (Action Planned or Taken)	Target Date
5.	Roles and responsibilities over pre-approved special authority should be clearly defined.	1. Review/prioritise list of medications with prescriber exemptions (as listings change, new meds are reviewed, new projects planned, etc.) 2. Establish a framework for oversight and planning for change going forward 3. Convert to CPA/benefit/LC/ where it makes sense. (link to Rec. #2) 4. CPA and exemption review annually, risk assessment and strategic actions post	FY2019/20 Q3 (1 & 2) Already in progress (3)
6.	The Special Authority unit should establish a risk-based approach for monitoring, oversight, and quality assurance over all special authority approvals.	Current CPA monitoring plan involves yearly risk-based evaluation (e.g. magnitude of coverage when compared to other CPA's). This planned yearly review will be expanded to include a review of all exempted medications, to allow assessment of where CPA's fit in with other exemptions. • Use Business Intelligence to identify areas of low compliance and target SA work to try to improve in these areas	Jan. 2019

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Appendix 2 – Detailed Action Plan (continued)

Rec. #	Recommendations	Management Comments (Action Planned or Taken)	Target Date
7.	The Special Authority unit should ensure information is securely retained and user accesses regularly reviewed.	1. Work with IT services branch to ensure SA has appropriately secure environment 2. LAN access to be reviewed quarterly and at staff changes 3. eSA project to include regular review of security and user access 4. Digital Health Strategy to inform strategies and functions related to information sharing, access and patient component…in future. TBD	In progress (3)
8.	The Special Authority unit should develop a business case to assess costs and benefits of technological solutions.	Done. eSA project presentation to EPB Oct 2017. Awaiting funding decision.	July 2018

The Detailed Action Plan represents the Special Authority unit's response to the issues identified and the eight recommendations detailed in the 2018 report: *Review of PharmaCare Special Authority*. This document was prepared by the Special Authority unit and submitted to Internal Audit & Advisory Services to be included as an Appendix to the report.