Quality Assurance Program Guide

Ontario College of Pharmacists
Putting patients first since 1871
# Quality Assurance Committee Orientation Manual

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Quality Assurance Program

Overview

An overview of OCP’s Quality Assurance Program is provided in the chart below.

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Part A – patient care; Part B – no patient care
Two-Part Register

Voluntary Election

Each year upon completing their annual renewal, pharmacist members of the College will confirm their election into either of two parts of the Register, Part A or Part B.

Part A

Part A is the "patient care" part of the College Register. Pharmacists electing into Part A are retrospectively declaring that they have worked a minimum of 600 hours in patient care over the past three years as part of the annual renewal process. Currently pharmacists practicing patient care in any Canadian (or United States) jurisdiction may elect into Part A of the Register.

In addition to the required practice hours, pharmacists in Part A of the Register are required to:

1) maintain a learning portfolio
2) complete the Self-Assessment when randomly selected to do so
3) participate in the Peer Review when randomly selected to do so

Patient Care

The College considers that a pharmacist is providing "patient care" if they are providing pharmacy services to the public. This includes: dispensing, selling and/or compounding drugs and providing nonprescription drugs, health care aids and devices; providing information related to drug use; and directly supervising the part of a pharmacy where drugs are kept. (Regulations to Pharmacy Act, 1991 section 45)

With the new expanded scope regulations (Regulations to Pharmacy Act, 1991 sections 31-39), the following activities have been added to the practice of pharmacy:

a) the custody, compounding, dispensing and prescribing of drugs;
b) the provision of health care aids and devices;
c) the provision of information and education related to the use of anything mentioned in clauses (a) and (b); and
d) the promotion of health, prevention and treatment of disease, disorders and dysfunctions through monitoring and management of medication therapy

If as a pharmacist you engage in any of the following activities, you must elect to be in Part A of the Register.

- Counsel or dialogue with patients or their agents about medications including non-prescription medications and health care aids
- Provide information and education related to drug use, in the course of practicing the profession, directly to patients or their agents
- Perform either or both cognitive and/or technical functions of compounding or dispensing
- Supervise the compounding or dispensing function, as above
- Directly supervise the part of a non-accredited pharmacy where drugs are kept
- Review any prescription order for individual patients, or perform a patient profile or clinical review for an individual patient
- Administer, by injection or inhalation, medication to patients for education or demonstration
- Perform a procedure on tissue below the dermis
- Prescribe medications (initiating therapy or adapting / renewing therapy)
- Develop drug therapy protocols or policies directly related to drug therapy practices specific to the institutional setting in which you practise.

Part B

Pharmacists choosing Part B, the "no patient care" part of the Register, are declaring that they will not be providing patient care. This means that the member cannot work as a pharmacist in an Ontario pharmacy or perform any of the controlled acts that are associated with providing pharmacy services to the public.

A pharmacist in Part B of the Register may not:

- Work in a pharmacy as a pharmacist
- Fill in as a pharmacist on an occasional basis
- Provide information related to drug use to patients, agents or health care providers in the course of providing patient care as a pharmacist, or
- Be the designated manager of an accredited pharmacy

Although a pharmacist electing to Part B cannot be the designated manager of an accredited pharmacy, he or she can, as a registered pharmacist in Ontario, be an owner of a pharmacy, or a director of a corporation owning a pharmacy in Ontario. Pharmacists in Part B may also be the manager, director or supervisor of a pharmacy department in a hospital or health care facility, and could therefore supervise pharmacists and technicians in an institutional setting but may not provide patient care.

Those pharmacists who provide information related to drug use in their usual workday, but who do not provide patient care while practising the profession, would be expected to elect into Part B of the register. Examples could include, but not be limited to, pharmacists currently working in: administration (including College staff), academia, government, the pharmaceutical industry, and consulting firms. However, such pharmacists wishing to remain in Part A of the register could do so provided that they fulfill the practice requirement of 600 hours of patient care while practising the profession, over a three-year period.

Pharmacists in Part B, like those in Part A, are required to maintain a record of continuing professional development (i.e. a learning portfolio), and are expected to maintain the ethical and practice standards of the profession set by College Council. Pharmacists in Part B are not required to meet the minimum practice requirement of
600 hours over three years, nor will they be subject to random selection for quality assurance activities (i.e. Self-Assessment or Peer Review).

**Movement from Part A to Part B**

A member may move from Part A to Part B of the Register at any time simply by notifying the College, in writing, of his or her intent to do so. The change in election would take place immediately or on the effective date provided by the member.

**Movement from Part B to Part A**

A member may move from Part B to Part A of the Register by notifying the College, in writing, of his or her intent to do so and by successfully undergoing the College’s Peer Review. Peer Reviews are currently held four times yearly. Every attempt is made to ensure that a member wishing to undergo a Peer Review for the purposes of transferring from Part B to Part A is promptly scheduled into the next available administration.

Members who have not notified the College otherwise, but who seek to change their election from Part B to Part A during the annual renewal process, will be contacted by staff to confirm that a change in election is indeed being requested, and to schedule the member into the next mutually convenient Peer Review. Current policy allows a member in Part B to work in a pharmacy under the direct supervision of a pharmacist in Part A, for the purposes of preparing for the Peer Review, for a period of time not to exceed two consecutive six-month periods without the approval of the Quality Assurance Committee. In order to do this, pharmacists in Part B must notify the College in writing of their intention, citing the name of the pharmacist under whom they will be working, the name and address of the practice site, and the anticipated start and finish dates. Members are required to be enrolled in an upcoming Peer Review prior to commencing work.

A member will be transferred from Part B to Part A provided they successfully complete the Peer Review and also satisfy the educational and practice requirements that may be specified by the Quality Assurance Committee. Members are considered to have successfully completed the Peer Review if they met or exceeded the set standard in the following areas of assessment: clinical knowledge, gathering information, patient management and follow-up, and communication skills. Generally, the Quality Assurance Committee will not transfer a member from Part B to Part A unless it is satisfied that he or she has met or exceeded the standards in both the areas of clinical knowledge and communication skills.

**Powers of the Quality Assurance Committee to transfer from Part A to Part B**

The Quality Assurance Committee has the discretion to transfer a member from Part A to Part B of the Register by the authority granted under Section 47(3) of the College's quality assurance regulation, which reads:
If a pharmacist listed in Part A fails to undergo a required practice review, the Committee may transfer the pharmacist to Part B after giving him or her a reasonable opportunity to make written submissions.

This section would apply to any member who fails to participate in either Phase I (Self-Assessment) or Phase II (Peer Review) of the Practice Review process after being randomly selected to do so. The Quality Assurance Committee would only act under the authority of this section in instances where repeated communications from the College to a member have gone unanswered. Section 47(3) gives the Quality Assurance Committee the power to transfer a member from Part A to Part B in such instances after giving him or her reasonable opportunity to make written submissions to the Quality Assurance Committee. Members must be given 14 days in which to make written representation or to request an appearance before the Quality Assurance Committee in order to make an oral submission to the Quality Assurance Committee citing reasons why they should not be transferred into Part B.
Learning Portfolio

The OCP Learning Portfolio is a tool that assists members in planning and documenting their learning activities. The Learning Portfolio Tool, available on-line through the Continuing Professional Development (CPD) Portal, consists of four sections: Education Action Plan, Continuing Education (CE) Log, FAQ Log and Professional Profile.

All members of the College, whether electing into Part A or Part B, are expected to engage in continuing professional development and maintain a record of their learning. Members may use the Learning Portfolio available through CPD Portal; however, any method of filing or recording one's continuous learning activities is acceptable as long as it is current.

Members are required to retain their learning portfolio records and supporting documents for a minimum period of five years.

To access Learning Portfolio Tool:

1. Visit the OCP website at [www.ocpinfo.com](http://www.ocpinfo.com).
2. Click on the CPD Portal button located in the lower left hand corner of the OCP homepage, under FAST TRACK, to bring you to the sign-in page.
3. Your User Name is your OCP number.
4. Your Password is your date of birth in the following format MMDDYY (use numbers only). For example, if your birth date is September 14, 1980 your password would be 091480. (Note: your password can be changed once you have logged-in.)
5. Click on Learning Portfolio
Self-Assessment

The Self-Assessment is a tool that assists members in identifying their learning needs (both those to maintain competency and those to advance professionally) and creating a plan for learning. The Self-Assessment Tool is also available on-line through the Continuing Professional Development (CPD) Portal.

Every year, 20% of pharmacists in Part A of the Register will be randomly selected to complete the Self-Assessment Tool (Phase I of the Practice Review). This means that approximately 2,400 pharmacists will be selected to participate each year, and every pharmacist in Part A will be selected to participate once in every five year cycle. Members who are randomly selected for this process are required to complete the Self-Assessment Tool and notify the College of completion within eight weeks. Although members are only required to complete the Self-Assessment once in every five year cycle, members are encouraged to complete it voluntarily on a yearly basis.

The Self-Assessment Tool is available on-line as part of the Continuing Professional Development (CPD) Portal. To access the Self-Assessment Tool:

1. Visit the OCP website at [www.ocpinfo.com](http://www.ocpinfo.com).
2. Click on the CPD Portal button located in the lower left hand corner of the OCP homepage, under FAST TRACK, to bring you to the sign-in page.
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4. Your Password is your date of birth in the following format MMDDYY (use numbers only). For example, if your birth date is September 14, 1980 your password would be 091480. (Note: your password can be changed once you have logged-in.)
5. Click on Self-Assessment Tool
Peer Review

The Peer Review (Phase II of the Practice Review) is a clinical knowledge and practice-based assessment which is an integral part of OCP’s quality assurance program for pharmacists.

Pharmacists in Part A of the Register are randomly chosen to participate in the Peer Review. Currently, approximately 240 pharmacists per year are required to undergo the Peer Review. Peer Reviews are held in Toronto at the College four times a year.

The Peer Review is an assessment based on the standards of practice. It lasts approximately six hours and consists of:

- Orientation session (30 minutes)
- Learning Portfolio sharing session (60 minutes)
- Clinical Knowledge Assessment (CKA) consisting of 18 cases each followed by three multiple choice questions (120 minutes)
- Standardized Patient Interviews (SPI) during which interactions with trained standardized patients in 5 case scenarios will be assessed by peer assessors (75 minutes)
- General feedback session at the end of the review process

Further information regarding the Peer Review is available below:

Peer Review Preparation
Peer Review Components
Random Selection, Exemptions and Deferrals
Reporting of Results
Remediation – Peer Support Group
Remediation – Professional Development Workshop
Peer Review Preparation

The best preparation for the Peer Review is active practice. The following tools may also be useful:

- Informational video about the Peer Review
- Sample clinical knowledge cases and questions
- Sample pharmacist – patient interviews
- “Ten Minute Patient Interview” CE including a sample checklist

For access to the above tools, see http://www.ocpinfo.com/client/ocp/OCPHome.nsf/web/Peer+Review+Preparation.
Peer Review Components

In the Peer Review, there are four main areas in which candidates are assessed: 1) Clinical Knowledge 2) Gathering Information 3) Patient Management and Follow-up and 4) Communication Skills. The Clinical Knowledge score is derived from the Clinical Knowledge Assessment. The other three components—Gathering Information, Patient Management and Follow-up, and Communication Skills—are derived from the Standardized Patient Interviews.

(1) Clinical Knowledge Assessment (CKA)

The “Clinical Knowledge Assessment” (CKA) component of the Peer Review is a case based, open-book multiple choice question examination. It represents relevant, common situations encountered in everyday pharmacy practice. The CKA cases have been written and reviewed by practicing pharmacists to ensure that they are relevant and reflect the type of cases that are seen regularly in everyday practice.

The following references will be provided to the candidates during CKA of the Peer Review:

Individual References Provided:
- Compendium of Pharmaceuticals and Specialties (CPS)
- Therapeutic Choices
- Patient Self-Care
- e-cps / e-therapeutics

Shared References Provided:
- Natural Medicines Comprehensive Database
- Paediatric Dosage Handbook
- Drugs in Pregnancy and Lactation
- Medical Dictionary

Candidates may bring additional reference texts and a calculator.

The CKA is a computer-based assessment. Internet access is available on the laptops provided. Mobile devices are permitted (e.g. laptop computers, personal digital assistants etc.); however, OCP wireless internet access is not available and candidates are responsible for the independent battery power source of their computer device(s).

Standardized Patient Interviews (SPI)

The “Standardized Patient Interviews” (SPI) case scenarios have also been written and reviewed by practicing pharmacists to ensure that they are relevant to general pharmacy practice.
The following references are provided to the candidates during SPI of Peer Review:
  o *Compendium of Pharmaceuticals and Specialties* (CPS)
  o *Therapeutic Choices*
  o *Patient Self-Care*
  o *e-cps / e-therapeutics*

Candidates may bring additional reference texts. Internet access is available on the laptops provided. Mobile devices are permitted (e.g. personal digital assistants etc.); however, OCP wireless internet access is not available and candidates are responsible for the independent battery power source of their computer device(s). Note that laptop computers are not permitted.

In each of the five SPI cases, a standardized patient will present to the candidate with a prescription or issue. The candidate will be expected to provide usual and customary pharmacy care services. A trained peer assessor (one for each case scenario) will observe and assess the candidate’s interaction with each of the five standardized patients (in the five cases respectively) on three components: Gathering Information, Patient Management and Follow-up, and Communication Skills.

The peer assessors are practicing pharmacists that have been appointed by the Quality Assurance Committee. These individuals, who represent various practice settings, have been specially trained by a consultant to assess members in a standardized fashion.

**2) Gathering Information**

The “Gathering Information” component of the standardized patient interviews should flow smoothly in an organized, logical and systematic fashion, with the candidate leading the process confidently while encouraging the patient to ask questions and give input. When patients raise an issue of concern which signals a “red flag” in the candidate’s professional opinion, it is important to pursue the issue further, being as thorough as possible and making sure that all necessary information about the potential drug-related problem is gathered.

**3) Patient Management and Follow Up**

“Patient Management and Follow Up” strategies consist of addressing the most relevant drug-related problems and communicating clearly to the patient in lay terms. This includes discussing contributing factors such as lifestyle issues and devising a plan together to resolve or prevent similar situations from occurring. Patient education is the key when providing practical recommendations to help them make better health care choices. The conclusion of this component of the interview should include reviewing important educational points and providing the patient with an opportunity to ask questions to clarify any outstanding issues. Follow up may be quite informal, for instance, a simple invitation for the patient to call with any
concerns, or sometimes it may be more important for the pharmacist (candidate) to contact the patient within an appropriate time frame.

(4) Communication Skills

Candidates are expected to demonstrate their ability to communicate through assessment in four domains:

- verbal expression
- non-verbal expression
- empathy
- organization of the interview / coherence

When “communicating” with a patient, it is important to remain professional, be clear and concise and use language that the patient will understand. Candidates should demonstrate empathy for the patient's situation, and be willing to help with their drug-related needs. Well-developed listening skills are essential for an effective patient interview. When patients express themselves, candidates should pay attention to their verbal and also their non-verbal messages (for example, facial expression, and body language). Pharmacists may sometimes be too focused on the facts of a situation and miss important patient cues as to how patients are feeling and what really matters to them. Interacting with patients is always a two-way communication where both participants equally contribute to the discussion.

When seeking resources to develop patient interview skills, it is best to combine print resources with live, interactive learning opportunities, as these skills require practice to develop.
Random Selection, Exemptions and Deferrals

All Pharmacists in Part A of the Register, excluding those who are exempt, may be randomly chosen to participate in the Peer Review.

Exemptions

- Members who have recently passed the Pharmacy Examining Board of Canada Qualifying Examination including the OSCE component are exempt from random selection for the Peer Review for a period of ten years from the date of the examination.
- Members who have successfully completed the Peer Review are exempt from random selection for the Peer Review for a period of ten years. Should they be chosen for Peer Review in the following five years, they will be assessed with the clinical knowledge assessment only.
- Pharmacists participating in areas of development and implementation of the Peer Review process, including assessors, Quality Assurance Committee members, and question and case writers, reviewers, and standard setters, are exempt from random selection for the Peer Review for a period of two years from the date that they cease to be involved in the Quality Assurance program and process.

Deferral Requests

Every attempt is made to be as flexible as possible when scheduling the Peer Reviews, and deferrals up to one year have been granted in certain instances. Such instances have included illness of a member or one of their family members, maternity / paternity leave, or conflicting work or travel plans.

As a matter of administrative policy, a member selected is usually granted a first deferral when requested. If the Manager feels the member is trying to avoid his or her obligation, he or she will be referred for consideration to the Quality Assurance Committee and so notified of the referral so that they will be provided with 14 days notice to give written or oral submission to the Quality Assurance Committee. The Quality Assurance Committee may, upon consideration of a member’s failure to undergo the Peer Review within a year of being randomly selected, direct staff to defer the date of review to a later date, or it may propose to transfer the member into Part B (see Powers of the QA Committee to transfer from Part A to Part B above).

Reimbursement for Participants in the Quality Assurance Peer Review

Members of the College who are randomly selected for the Peer Review, who are practicing in Canada, are reimbursed for reasonable expenses incurred in traveling to the College upon submission of all receipts (including GST) according to the College’s reimbursement policies and guidelines.

http://www.ocpinfo.com/client/ocp/OCPHome.nsf/web/Peer+Review+Preparation
Members who Resign and are Reinstated

If a member resigns after having been selected for the Peer Review; their obligation to participate in the process will cease with their resignation. However, should that member be reinstated, he or she shall resume his or her position in the quality assurance process and shall be expected to continue as a full participant.

Members who are Selected for the Peer Review for a Second Time

The number of candidates randomly selected for the Peer Review for the second time is limited to no more than five percent of the total number of candidates selected per Peer Review session.

As outlined above, pharmacists that successfully complete the Peer Review are exempted from the random selection process for ten years after completion, and for the following five years, pharmacists selected for a second time are only required to undergo the Clinical Knowledge Assessment. Although it is important to maintain vigilance for those pharmacists that have completed the Peer Review, it is also important to remember that resources for the quality assurance program are finite. The number of candidates selected for the Peer Review for a second time has recently surfaced as an issue because, as the number of candidates in this pool grows, so does the potential to re-select these candidates. The Quality Assurance Committee feels that the majority of resources should be spent on assessing initial candidates, and thus, have made the decision to limit the number of candidates selected for a second time.

Volunteers for the Peer Review

A pilot program allowing pharmacists to volunteer to undergo the Peer Review began in February 2010.

The benefits of allowing volunteers include:

- Maximizing use of available space at each Peer Review (thus maximizing use of College funds)
- Enabling pharmacists to participate in the Peer Review process as assessors or as case developers. Current policy indicates that pharmacists invited to be part of the Peer Review process are required to have completed the Peer Review. A volunteer policy allows pharmacists, who have not yet been randomly selected, to complete the Peer Review requirement and then be eligible to participate in the above described working groups.

The volunteer program will be in addition to the usual random selection process, with the aim of maximizing resources.
Volunteers are required to sign an undertaking which states that he / she will comply with all the same laws / regulations and obligations as though he / she were randomly selected. The contract indicates that, in the event of failure to meet standards, the volunteer pharmacist will be required to go through remediation. The undertaking also outlines the exemption policy (which is the same as that for randomly selected pharmacists).

Pharmacists interested in volunteering to undergo the Peer Review are placed on a volunteer list and selected on a first come, first served basis. The volunteer pharmacist is given notice of potential participation one to three weeks prior to the Peer Review.
Reporting of Results

Approximately six weeks following the Peer Review, the individual results are presented to the Quality Assurance Committee. The Quality Assurance Committee considers individual results by candidate number only, and as such, is unaware of the identities of individual candidates. In this way, all candidates are considered in the same fashion and treated equally.

Once the direction of the Quality Assurance Committee has been received, College staff will send results letters to all candidates who have met or exceeded the standards in all four areas of assessment, and to those candidates who may have fallen below one or more of the standards but where follow-up is not indicated. These letters are sent approximately six to eight weeks after each Peer Review administration. Where it is the view of the Quality Assurance Committee that remediation and/or reassessment is required of a candidate, the candidate will be contacted by written communication stating the view of the Quality Assurance Committee and offering the candidate the opportunity to meet with a Peer Support Group.

Candidate Performance Report

Attached to the results letter, each candidate receives a performance report. This report includes a detailed explanation about how to interpret and understand the information enclosed. It includes:

- A performance summary table that outlines their score in each result area along with the Minimum Performance Level (MPL) and their status (Met Standard or Fell Below Standard).
- A table of results from the Clinical Knowledge Assessment broken down by case and a guide outlining the clinical focus of each case along with a comparison against other candidates from the same administration.
- A table outlining their performance in the Gathering Information Domain in the Standardized Patient Interviews with a comparison against other candidates from the same administration.
- A table outlining their performance in the Patient Management and Follow up Domain in the Standardized Patient Interviews with a comparison against other candidates from the same administration.
- A table outlining their performance in the four Communication domains scored with a comparison against other candidates from the same administration.

Decisions Regarding Peer Review Results

Each candidate is considered on an individual basis with respect to his or her Peer Review results. Members have the right to make a written or oral submission to the Quality Assurance Committee following the receipt of their report and Committee
decision. Historically, the Quality Assurance Committee has given staff the following direction upon its decisions.

- **Candidates meeting or exceeding standards in all four components**
  Successful candidates receive a letter which congratulates them on successful completion of the Peer Review process and invites them to contact a designated staff person should they have any questions or concerns. These individuals are also invited to participate in the Peer Review development process or be trained as an assessor.

- **Candidates falling below the standard in one component**
  Candidates failing to meet the standard in one component of the Peer Review (either Gathering Information or Patient Management and Follow up) will be informed that the Quality Assurance Committee encourages them to review the list of educational resources included with their results letters and participate in any programs that may assist them in enhancing their professional knowledge and skills, especially in the noted areas. In some cases, the Quality Assurance Committee may recommend or require a member to prepare a written education action plan and ask for subsequent evidence or confirmation that the action plan has been successfully completed. These candidates have not been required to undergo reassessment.

  Candidates who fall below the standard in the assessment area of Clinical Knowledge or Communication Skills are generally asked to submit a written education action plan, undertake their planned remediation and be reassessed in the clinical knowledge component or the standardized patient interview component of the Peer Review.

- **Candidates falling below the standard in two or more components**
  These candidates will be required by the Quality Assurance Committee to submit an education action plan to the College within four to six weeks upon the receipt of their results. The action plan should outline the remedial education activities that they intend to pursue for the purpose of enhancing their professional knowledge and skills in the areas that have been identified in their Peer Review. These candidates are also offered the opportunity to meet either in person or by teleconference with a Peer Support Group to discuss their plans for remediation and subsequent reassessment. Generally, candidates schedule their reassessments within a year, but this time frame is flexible depending on the candidate's comfort level and degree of readiness.

**Role of Quality Assurance Committee Members in the Peer Review Process**

It has been determined that it is a conflict of interest for a Committee Member to be an Assessor. This will avoid situations of bias when candidate results are considered and decisions are subsequently made. The Committee agreed that members of the
Quality Assurance Committee should be encouraged to participate in other non-assessment components of the Peer Reviews such as the educational session on the learning portfolios, and act as invigilators for the written test of clinical knowledge. It was further agreed that members of the Quality Assurance Committee could continue to take part in the Quality Assurance process as question and case writers or as standard setters.
Peer Support Group

One of the supporting resources for remedial candidates is access to a Peer Support Group. This group is comprised of two education minded pharmacists and a staff resource. Generally each remedial candidate is provided a 45-minute session with the Peer Support Group.

At these meetings, support is provided to help the remedial candidate develop an education action plan, set a target date for reassessment, and discuss any issues which may be preventing the individual from participating in remedial activities and ultimately achieving success in the Peer Review assessment.

Peer Support Group is generally offered three times per year at the College.

Role of the Peer Support Group

- To ensure the candidate understands the importance of continual professional development as a responsibility of being a health care provider
- To provide support and encouragement regarding the candidate's ability to successfully remediate
- To assist the candidate in articulating his/her learning needs and guide them towards appropriate learning opportunities
Professional Development Workshop

The Professional Development Workshop is a shared learning workshop conducted by the Ontario College of Pharmacists and the Standardized Patient Program of the University of Toronto’s Centre for Research in Education. It is intended to promote a better understanding of the learning process and skills needed to provide pharmaceutical care.

The Workshop is divided into two sessions: (1) Clinical Knowledge and (2) Communication Skills through Standardized Patient Interactions. Both sessions will include small group interaction with colleagues and facilitators to provide an opportunity to learn from peers. Candidates are strongly urged to register for the complete workshop if they are seeking to upgrade their skills in both the Clinical Knowledge and Standardized Patient Interaction components of the Quality Assurance Peer Review.

The Professional Development Workshop is generally offered twice a year at the College.