THE COLLEGE OF FAMILY PHYSICIANS OF CANADA



LE COLLÈGE DES MÉDECINS DE FAMILLE DU CANADA

Management of Relationships With the Health Care/ Pharmaceutical Industry

JANUARY 2019

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This document was prepared by: Jeff Sisler, Executive Director, Professional Development and Practice Support Jennifer Campbell, Director, Conferences and Events Amy Outschoorn, Director, Continuing Professional Development Peter Thomlison, Publisher, *Canadian Family Physician*

The following individuals provided invaluable support in the preparation of this document:

Jessica Black, Manager, Certification, CPD Department

Lucy Nini, Advertising Coordinator, Canadian Family Physician

Jasmina Vicentijevic, Business Analyst, CPD Department

BACKGROUND

In November 2013 the College of Family Physicians of Canada (CFPC) Board approved the report <u>The</u> <u>CFPC's Relationship With the Health Care/Pharmaceutical Industry</u>.¹ The report was prepared by a task force chaired by Dr. Sandy Buchman. The desired outcomes of the task force's work were to:

- Guide interactions between the CFPC and its provincial Chapters regarding the health care/pharmaceutical industry (HPI)
- ► Maintain the trust of CFPC members and their patients
- ► Identify clear, strong principles, policies, and practices to support CFPC members
- Guarantee that all members who abide by the principles can engage in the full range of leadership opportunities and activities of the College

The report included 20 recommendations addressing areas that include conflict of interest (COI), financial relationships, marketing, and access to information. The task force recommended adhering to the following principles:

- Trust—the CFPC's primary obligation to members and their patients and the management of COIs
- ► Transparency—full disclosure of relationships with the HPI
- ► Independence—no HPI involvement in the CFPC's direction and decision making
- ► Accountability—in policies related to relationships with the HPI and resolution of all COIs
- ► Fairness—in declaring and resolving COIs

THE HEALTH CARE/PHARMACEUTICAL INDUSTRY (HPI) IS DEFINED AS

for-profit entities that develop, produce, market, resell, or distribute drugs, devices, products, or other health care goods, services, or therapies that may be prescribed to patients or ordered by doctors in the diagnosis, treatment, monitoring, management, or palliation of health conditions.¹

The definition of the HPI provided above was used in the CFPC's 2013 report and modified in the <u>2018 National Standard for Support of Accredited CPD Activities</u>² (National Standard) that the CFPC endorsed. The National Standard was developed by a working group that included members from the CFPC, the Committee on Accreditation of Continuing Medical Education (CACME), the Conseil québécois de développement professionnel continu des médecins, the Fédération des médecins spécialistes du Québec, and the Royal College of Physicians and Surgeons of Canada. The intent of the National Standard is to safeguard the integrity of certified CPD activities from the influence of sponsoring organizations that could lead to bias by enforcing an arm's-length relationship between program sponsors and program developers. The term **commercial interest** is used in the National Standard, so the terms HPI and commercial interest are used interchangeably in this report. The direction the CFPC Board set in 2015 was to determine short-, medium-, and long-term activities for the management of relationships with the HPI for greater control, increased financial independence, and enhanced transparency by the CFPC. This direction has ensured that the CFPC continually assesses its policies and performance regarding this relationship.

In June 2015 the CFPC Board approved these motions:

THAT the Board direct the relevant Board-mandated committees overseeing continuing professional development (CPD), Family Medicine Forum (FMF), and *Canadian Family Physician (CFP*) to report on the implementation of the approved Nov 2013 Task Force recommendations.

FURTHER THAT the Executive Directors with responsibility for relevant program areas report in November 2015 and annually thereafter to the Board.

This report includes information about the CFPC's fiscal years 2016–2017 and 2017–2018.

1. Family Medicine Forum

Under the leadership of its national FMF committee that represents Chapters and Sections, the CFPC supports and strictly manages its relationship with the HPI in all matters related to FMF. The FMF Committee seeks continual improvement, self-assessment, and external feedback in the ongoing management of this relationship, which respects the principles of the 2013 task force report.¹

FMF ENHANCEMENTS: OVERVIEW

Family Medicine Forum Forum en médecine familiale

Since 2013 the FMF Committee has developed policies and guidelines to manage the relationship between the CFPC and the HPI, as follows:

- All FMF presenters, vendors, and sponsors are required to comply with the following guidelines:
 - <u>Mainpro+ Certification Standards</u>³
 - <u>COI Quick Tip</u>,⁴ COI slide templates,⁵ and <u>COI Form</u> requirements⁶
 - Guidelines for Physicians in Interactions with Industry⁷
 - <u>The National Standard</u>²
 - Family Medicine Forum Policies and Guidelines⁸
 - <u>Innovative Medicines Canada Code of Ethical Practices</u>⁹
 - And all amendments as required by provincial, national, and CFPC standards

- The FMF Committee will review these guidelines annually and enhance them as required
- All financial information will be disclosed fully post audit, with new tracking of all HPI revenues
- > All educational content will continue to be separate from the Exhibit Hall
- ► The Exhibit Hall will continue to be promoted as a marketplace/marketing area with appropriate disclaimers
- ► All HPI activity will be restricted to the Exhibit Hall or public, non-CPD areas only
- The scientific program will be fully separate from the Exhibit Hall guide in print, online, and in the FMF App
- FMF will continue to have an HPI-free main aisle in the Exhibit Hall for direct access to food
- ► FMF will adhere to provincial rules on a national level (e.g., no passport contests, bag inserts, etc.)

NEW FMF GUIDELINES

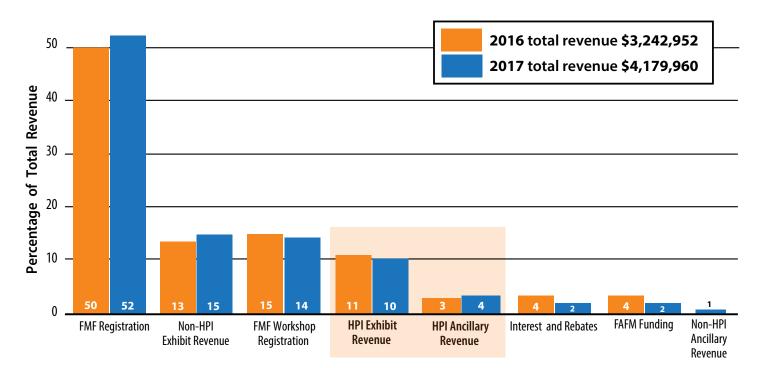
To continue to manage HPI involvement at FMF successfully, the FMF Committee approved several new guidelines in 2018:

- ► Guidelines for a managed relationship with commercial interests (internal document)
- Enhanced Vetting Guidelines for Commercial Interests (includes monitoring and enforcement strategies; internal document)
- ► Family Medicine Forum Policies and Guidelines¹⁰, includes:
 - FMF Exhibitor/Sponsor Code of Conduct
 - Guidelines for Samples, Incentives/Giveaways and Contests
- ► <u>FMF Presenter Guidelines¹¹</u>
- ► FMF Speaker Code of Conduct¹²
- > Ancillary guidelines developed to adhere to the National Standard (internal document)
- FMF audit tool to monitor quality and adherence to all standards (internal document)

FMF Committee members and CFPC staff are committed to ensuring they monitor, manage, maintain, and seek continual improvement in adhering to all applicable standards regarding HPI involvement at FMF.

FMF REVENUE REPORTING

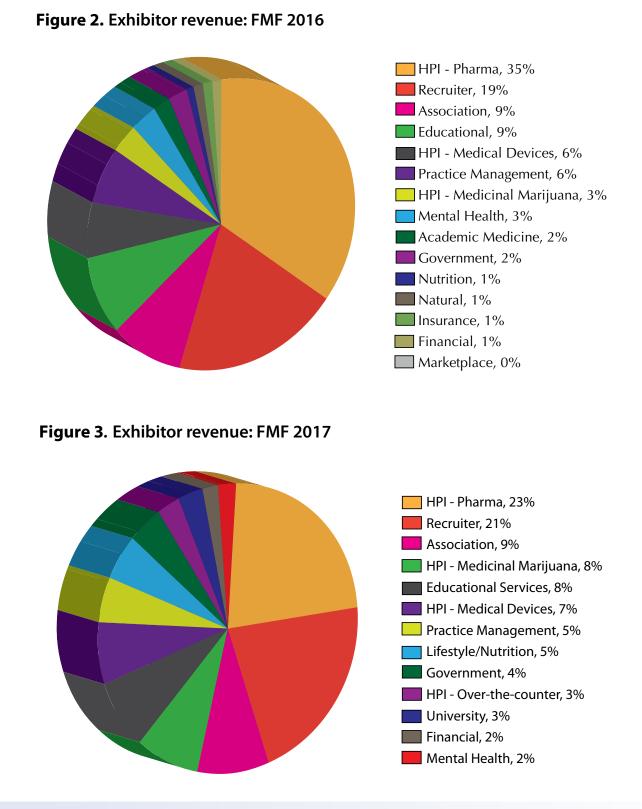
To comply with the National Standard, all FMF revenues will be fully disclosed to, reviewed by, and approved by the FMF Committee, the CFPC's Finance and Audit Committee, and the CFPC Board of Directors. All commercial interest revenue will be tracked and reported annually.





KEY FINDING

Revenue sources classified as HPI represented 14 per cent of the total revenues at FMF 2017, which was unchanged from FMF 2016 (Figure 1).



KEY FINDING

At FMF 2016 the HPI accounted for 44 per cent of exhibitor revenue (Figure 2). This dropped to 41 per cent at FMF 2017 (Figure 3).

FUTURE ENHANCEMENTS AND CONTINING IMPROVEMENTS

Several additional enhancements are currently under way:

- 1. The CFPC will enhance the FMF 2019 call for abstracts to:
 - Ask presenters to disclose further all COIs and affiliations
 - Ask speakers to declare how they will mitigate their COIs
 - Confirm all slide content is developed by a physician
- 2. The Upskilling Committee led by Dr. Janice Harvey (CPD Department) developed a Mainpro+[®] certified educational program for scientific planning committees. This pilot workshop was held at FMF 2018, with many FMF Committee members attending.
- 3. The CFPC will continue to:
 - Restrict **all** commercial activity to the Exhibit Hall and non-educational areas
 - Explore new revenue streams (e.g., live streaming) to mitigate potential losses in revenue
 - Seek delegate feedback about preferences regarding maintaining a managed relationship with the HPI (in our 2017 survey 57 per cent of delegates said they preferred to **keep** HPI exhibits; 16 per cent preferred to **eliminate** them; and 27 per cent were **unsure**)
 - Collect data on the outcomes of the new HPI rules and guidelines
 - Seek feedback on all sessions and COI compliance to monitor and enhance quality

FMF SUMMARY

- CFPC staff and the FMF Committee are fully committed to meeting the highest standards for all aspects of FMF
- ► The CFPC is dedicated to maintaining a transparent, fair, trustworthy, independent, and accountable relationship with the HPI in accordance with task force recommendations and ongoing member preferences
- The CFPC is committed to ensuring the HPI has absolutely no influence on FMF education
- ► FMF maintains a very firm separation between the Exhibit Hall and all FMF educational areas
- The FMF Committee strives for continuous improvement with self-assessment, feedback, and best practices
- ► FMF will evolve and amend its guidelines, processes, and plans
- FMF will continue to deliver the highest-quality, evidence-based, unbiased family medicine CPD available in Canada and globally

2. Canadian Family Physician

BACKGROUND:

PHARMACEUTICAL ADVERTISING IN CANADA

Advertising revenue for most print publications has steadily declined in recent years, mainly due to a change in the consumption of print media since the introduction of the Internet. Many high-profile consumer magazines, such as *Maclean's*, have reduced their publication frequency while others, such as *Flare* and *Canadian Business*, are now digital only.



For medical journals such as CFP that rely mainly on

pharmaceutical advertising as a source of revenue, there are additional factors that have caused total advertising revenue to decline, including:

- Most pharmaceutical research is directed toward medications more commonly prescribed by medical specialists other than family physicians
- Similarly, "me-too" products (such as a new statin for cholesterol lowering that does not represent a significant improvement compared with existing drugs) are not being launched as they are unlikely to get formulary listing
- ► Most primary care prescriptions are filled using generic products
- Most major medical publications in Canada have a focus on family practice, which means CFP faces competition for advertising revenue

Another important reason for the decline in pharmaceutical advertising in the medical publications market is the closing in December 2016 of the premier agency for pharmaceutical advertising, Troutbeck-Chernoff.

The combination of these factors has challenged medical publishing in Canada. Many titles have reduced their publication frequency while others, such as *Parkhurst Review*, *Doctor's Review*, and *Canadian Journal of CME*, have ceased publication.

CFP REVENUE, 2016 TO 2018

CFP's revenue from the HPI is transparent. All ad rates are posted on the *CFP* website, <u>www.cfp.ca</u>. One could calculate the amount of HPI revenue by counting the number of pharma ads in the print issues of the journal and comparing it with the posted ad rate. Below are all sources of *CFP* revenue for the past two fiscal years and the percentages from the HPI, to allow comparison.

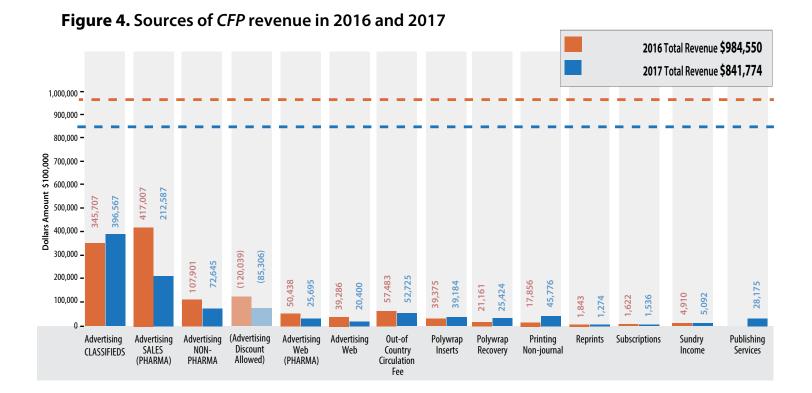
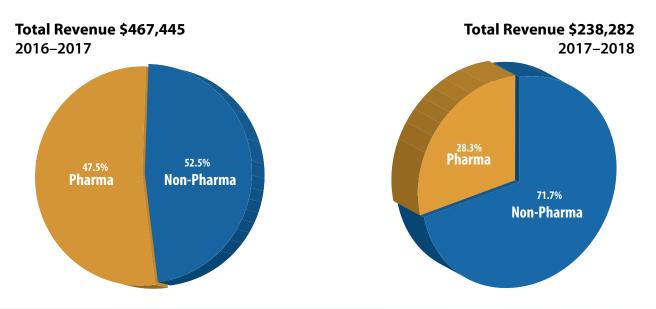


Figure 5. CFP revenue from the HPI



KEY FINDING

Revenue from pharmaceutical ads dropped to 28.3 per cent of total revenues in 2017–2018, down from 47.5 per cent in 2016–2017 (Figures 4 and 5).

OTHER POTENTIAL SOURCES OF REVENUE

1. New charges to non-member readers and authors

With the reduction in revenue from pharmaceutical advertising, *CFP* continues to seek other sources of revenue. Currently, the print edition of *CFP* is mailed to CFPC members as a benefit of membership. The online version is open access with no login requirement. If *CFP* were to implement a paywall system for all non-members, we could generate revenue from subscriptions to the website or pay-per-use for individual articles. There are benefits and drawbacks to implementing this option and *CFP* will investigate it thoroughly before making a final recommendation. *CFP* may also consider implementing author fees to help offset the costs of publication as this is a standard practice for many medical and peer-reviewed publications. Either of these options would mark a significant departure from *CFP* practices to date. However, due to the aforementioned factors as well as a requirement to manage our HPI relationships, *CFP* must pursue and evaluate other methods of revenue generation.

2. Publishing services

Another source of non-HPI revenue that the *CFP* team has developed is publishing services. In April 2018 *CFP* partnered with a third party to produce *CFP*'s first special edition, <u>Special issue on primary care of</u> <u>adults with intellectual and developmental disabilities</u>. Another special edition is scheduled for the first quarter of 2019.



3. Continuing Professional Development (CPD)

RECENT CHANGES IN CFPC POLICY AND THE EXTERNAL CPD ENVIRONMENT

The launch of Mainpro+[®] in June 2016 included substantial changes to the CPD credit requirements of the 42,900 family physicians who participate in the program. Mainpro+ participants are required to achieve 250 credits in a five-year cycle. Of these credits, 125 must be certified while the remainder can be from non-certified activities. One change introduced with Mainpro+ included a new restriction on programs eligible to be considered as non-certified activities. Mainpro+ participants are no longer permitted to claim Group Learning credits for non-certified activities that the HPI funded or developed. This reduces the incentives for participants to engage in programs that are more susceptible to influence from commercial interests.

Mainpro+ introduced more rigorous and transparent application and review processes for program certification. It described six Quality Criteria with new requirements for the design, development, and delivery of certified CPD programs. Mainpro+ features a stronger emphasis on levels of evidence supporting the information presented and on the application of learning to practice.

Adding to these new requirements, the National Standard2 came into effect on January 1, 2018. It includes seven elements and 29 sub-elements across these domains:

- ► Independence
- ► Content development
- ► Conflict of interest
- > Receiving financial and in-kind support
- ► Recognizing financial and in-kind support
- ► Managing commercial promotion
- ► Unaccredited CPD activities

The CFPC updated its Mainpro+ certification standards and application forms in 2017 to ensure they comply with the National Standard. The CFPC also introduced new policies defining eligible providers of Mainpro+ certified CPD. **This new policy excludes the HPI and its representatives from submitting programs for certification.** This means that as of January 2018, the CPD Department no longer receives revenue directly from the HPI.

CPD providers must confirm that relationships with financial sponsors comply with the National Standard and that the HPI is not responsible for providing honoraria or reimbursing speakers and scientific planning committee members for expenses.

KEY FINDINGS

- > The CFPC no longer permits the HPI or its representatives to submit programs for Mainpro+ certification
- *Effective January 1, 2018 the CPD Department will no longer receive revenue directly from the HPI*
- The CFPC no longer allows Mainpro + participants to claim Group Learning credits for attending non-certified activities funded, hosted, or developed by the HPI
- The CFPC championed the new National Standard that safeguards the integrity of certified CPD activities from the influence of sponsoring organizations that could lead to bias

ABOUT CPD REVENUES

The CFPC and its Chapters certify CPD programs for Mainpro+ credits. These programs, or activities, are submitted for review via the CERT+ application platform. Revenue is generated through two kinds of fees: **application fees** and **ethical review fees**. Fees are based on various factors: whether the program is seeking national or provincial certification; the number of credits per hour sought; and whether the program has for-profit financial support.

A second stream of revenue is derived from ethical reviews. Programs developed by, or with financial support of, for-profit organizations are subject to a session-by-session review each time they are to be delivered to ensure there is no commercial bias or marketing evident. It is important to note that for-profit companies include the HPI and other kinds of companies including independent medical education companies.

The CFPC's National Office receives revenue from:

- > Application fees charged for all nationally certified programs delivered in Canada
- > Application fees and ethical review fees for all programs delivered outside Canada
- \$50 from the application fee and \$50 from each ethical review fee charged for provincially certified programs; the rest of these revenues flow to the 10 CFPC Chapters

The current fees are outlined in Table 1.

Table 1. Mainpro+ certification application fees by program type

		nally Certified Pr grams delivered out	0	Provincially Certified Programs		
PROGRAM DELIVERY	ONE CREDIT PER HOURS	TWO CREDITS PER HOUR	THREE CREDITS PER HOUR	ONE CREDIT PER HOUR	TWO CREDITS PER HOUR	THREE CREDITS PER HOUR
With For-Profit Support \$850 \$950 \$1,050 \$650 N/A N/A The CFPC National Office uses the revenue from these fees in three ways: to pay the CFPC With the Structure of the CERTA With the Structure of the CERTA With the Structure of the CERTA						

CPD REVENUES FROM THE HPI: A CAVEAT ABOUT THE DATA

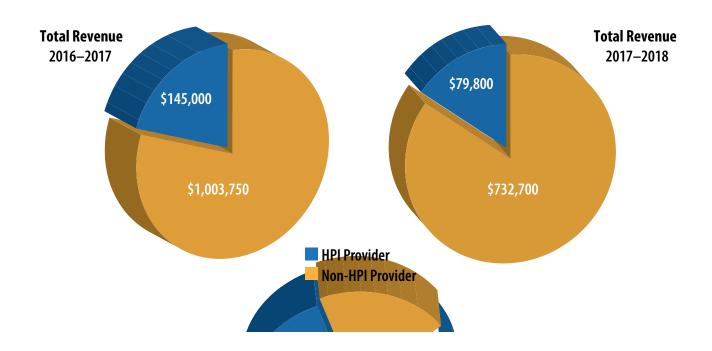
The launch of Mainpro+ and its new online certification platform (CERT+) provided the CFPC with an enhanced opportunity to collect and track data related to certified programs. However, caveats remain in interpreting the available information. Challenges have been identified in capturing the full picture of HPI funding in CPD:

- ➤ The data available do **not** include programs approved by university CPD offices that certify on the CFPC's behalf through their accreditation by CACME. University CPD offices began uploading information into the CERT+ system in June 2018, so it is anticipated that their data will be available in the next HPI report.
- ► Ethical review fees are not collected in all cases. University-certified programs are considered exempt from ethical reviews; only a single (rather than session-by-session) review is required for journal clubs and hospital/clinical rounds; and the first ethical review is provided at no cost for provincially certified one-credit-per-hour programs.
- Medical education companies are represented in the non-HPI category, although they can also work directly on contract for HPI companies. These companies are allowed to propose programs for certification only when they work independently.
- CPD providers in Canada seeking certification of their programs are allowed to receive financial or in-kind support from external organizations, including the HPI, as governed by the National Standard. The National Standard has created new restrictions that limit the role of the HPI to that of sponsorship and strengthen the independence of scientific planning committees.

- ➤ The CFPC asks for information regarding the presence or absence of for-profit support in the application form for Mainpro+ credits. In 2017–2018, 31 per cent of applications declared HPI support, 6 per cent declared other kinds of for-profit support, 44 per cent declared no outside funding, and 19 per cent declared funding that could not be defined with the information provided. In 2016–2017 these percentages were 35 per cent with HPI support, 7 per cent other, 40 per cent no outside funding, and 18 per cent undefined.
- When for-profit support is declared, these applications also receive ethical review each time the program is presented.

CFPC CPD DEPARTMENT REVENUES FROM THE HPI: THE DATA

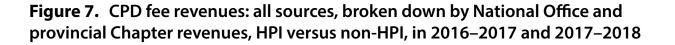
Figure 6. CPD fee revenues: all sources, National Office and provincial Chapters combined, HPI versus non-HPI, in 2016–2017 and 2017–2018

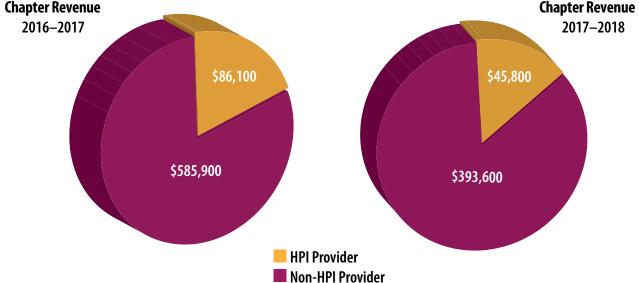


KEY FINDING

In 2017–2018, the CFPC and its 10 Chapters received \$79,800 in total revenue from HPI sources, which was 9.8 per cent of total revenues. This was a drop from \$145,000 (12.6 per cent) in the previous year (Figure 6).

National Revenue 2016–2017 558,900 5339,500 5339,500 HPI Provider Chapter Revenue 2016–2017 Chapter Revenue 2017–2018





KEY FINDING

In 2017–2018, the CFPC National Office received \$34,000 (9.1 per cent) and its Chapters \$45,800 (10.4 per cent) in revenue from HPI sources related to the review of CPD programs. These figures are down from 12.3 per cent and 12.8 per cent of National and Chapter revenues, respectively, in 2016–2017 (Figure 7).

CPD SUMMARY

HPI revenues now make up less than 10 per cent of revenues related to the certification of CPD activities for family physicians. This figure is expected to drop to zero in 2018–2019 since HPI companies are no longer eligible as CPD providers under the National Standard.

The CFPC's CPD Department is committed to managing its relationships with HPI organizations in an ethical and transparent manner while ensuring CFPC members and Mainpro+ participants continue to have access to high-quality and practice-relevant CPD activities. The launches of Mainpro+ in 2016 and the National Standard in 2018 have substantially changed how the CFPC manages its financial relationships with the HPI. The CFPC's National Committee on CPD continually reviews the College's CPD policies, including those relating to HPI relationships.

CONCLUSION

This report describes the revenues the CFPC received from the HPI for three key elements of physician education and information that it provides: FMF (14 per cent of total revenues in 2017), (*CFP* 28.3 per cent in 2017–2018), and CPD certification (9.8 per cent in 2017–2018). These revenues considered together are declining, most notably with a sharp reduction in HPI advertising in *CFP*.

These findings reflect active policy development and enforcement by the CFPC that have strengthened restrictions governing the role and potential influence of the HPI in all its programs. It also reflects broader trends in the HPI regarding marketing and advertising. The CFPC's vigilance springs from its 2013 task force report and subsequent Board motions. The Board's commitment to actively manage, monitor, and report on the CFPC's relationship with the HPI will continue.

Declining revenues from the HPI create a revenue gap that poses a challenge. The CFPC will rely on the diligence of its leaders and the support and counsel of its members as it identifies ways to sustain and expand these vital educational services in this new fiscal environment.



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