Supplementary Guidance on Identifying Pickup Copy for PAAB

With April 2022 Guidance on Submission Process and Format Requirement ("April 2022 Guidance") now in effect, the PAAB wanted to provide clarification about the nature and process of identifying pickup copy.

It is critical that the identification of pickup copy is done in a manner that supports review efficiency and that enables our admin staff to quickly assess the approximate percentage of new content. Ultimately, in order to be able to provide the benefits associated with the accelerated timelines and the new fee structure, we require client and agency participation in the form of adherence to the submission standards.

What is pickup copy?

- Copy that has been **previously approved by PAAB** is referred to as "**pickup copy**" when it is reused in another advertising/promotion system (APS).
- For content to be considered as "pickup" it needs to be **identical** (i.e., verbatim) and should be presented in a similar context (i.e. similar visual treatment and placement within the piece) to what was previously approved.

How do we identify pickup copy?

Pickup copy should be identified by **shading the copy** and **referencing the eFile,** as per the April 2022 Guidance:

- **Shading the pickup copy** in light yellow
  - **Note that the April 2022 Guidance used the word "highlighting". As clients use this term in different manners, it has created confusion. As such, we have updated the Guidance Document to refer to this process as 'shading'. However, in order to distinguish pickup copy from other revisions, the shading function should be used to properly identify pickup copy. For example, in Microsoft Word, this can be done using the "paint can" icon:**
    - This function can be found in the "Paragraph" section of MS Word's navigation bar:
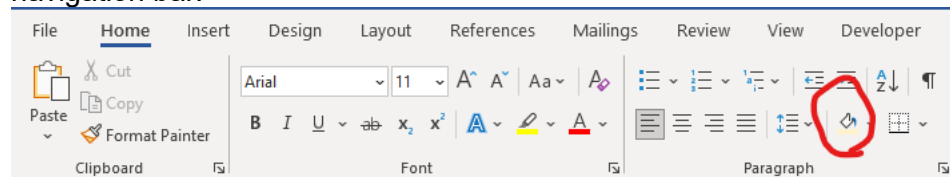
- Clearly **referencing the eFile** from which the content is picked up (i.e., the "backfile")
  - The relevant backfile annotation should appear in close proximity and be clearly identified
  - Note that this should be a recent backfile reflecting the most recently approved version of this presentation. If a change to copy was required (e.g., company required, PM change, PAAB request etc.), the updated file should become the quoted backfile and is now considered the "most recent file". It is the sponsors responsibility to ensure required/request changes in a file are applied to all new files and that the appropriate new backfile is referenced moving forward

An example of this process is shown in Appendix F of the April 2022 Guidance:

Email Envelope

Subject Line: Product ABC is now covered on formulary in your province (with criteria)!

Preview Text: Click inside to learn more.

Email Body

Copy:

Dear Dr. [Name],

We are pleased to announce that Product ABC is now covered on formulary in your province (with criteria). Click here (link URL: https://www.formulary.health.gov.on.ca/formulary/)for full coverage information. (Ref 1A, page 45)

[insert visual]

previously approved in efile 234567

As a reminder, Product ABC has a flexible dosing schedule. Patients can take one 10 mg tablet once daily or one 20 mg tablet weekly. Product ABC is to be taken with a full cup of water on an empty stomach. Patients should use the lowest dose and shortest duration appropriate. (Ref 2A, page 8)

Please consult see the Product Monograph for full dosing and administration information.

Product ABC is indicated for the treatment of disease XYZ in adults. (Ref 2B, page 3)

Consult the Product Monograph at www.ProductABC.ca/PM for important information on contraindications, warnings, precautions, adverse reactions, and dosing. The Product Monograph is also available by calling us at 1-800-xxx-xxxx.

Sincerely,

[Rep Name]

Email: [Rep Email]

A more detailed example of how pickup copy can be identified is provided in the Appendix. This example comprises of 4 copy decks:
1. An Efficacy Handout
2. An HCP Dosing Card
3. A new HCP Leave Behind that uses pickup content from #1 and #2, as well as new content.
4. An update to #3 that adds on and replaces content.

Important note: If your submission information is incorrectly identified or the copy is found to not be identical to what was previously approved, it will result in unexpected fee changes and/or delays for the eFile.

How do I highlight copy revisions between rounds of review?

- Note that the requirement to identify content changes between rounds of review within a file still applies (using highlights).
- The base "shading" for previously approved copy should remain throughout the review process. The reviewer still needs to be able to easily locate and assess the areas of the piece that are "new" content.
- The only highlighting that would be changing is in the sections which are "new content".
  - These sections would have no background shading and thus shading and highlighting would never overlap.

Best Practice Tip: How do I identify copy updates from previously approved versions of APSs?

When updating an APS with additional content revisions (i.e., exceeding the criteria for a Renewal Submission), please do the following:

- Identify pickup via light yellow shading. In an instance where you are identifying pickup copy from a parent file when submitting a child series submission, this would be shaded in light blue
- Leave revised content "chunks" unshaded, and show *specific revisions* with highlights (specific colour highlight is not required as long as it is clear and legible)
- Because all the pickup copy originates from the same backfile, a **precursory note** can be left at the top of the copy deck to inform the reviewer about the backfile, rather than citing the same backfile throughout the copydeck.

A detailed example of this can be found in Example 4 of the Appendix.

What are the expected benefits of this new process?

For all APS submissions: Improved review efficiency
Identifying pickup copy helps support review efficiency for the following reasons:

1. **Reviews may be carried out more quickly.**
   - Reviewers will be able to review copydecks more easily, since assessment of pickup copy does not typically require re-evaluation of the content's underlying evidentiary basis.
2. **Reviewers can optimize review timing.**
   - Admin staff can quickly assess the percentage of pickup copy to better allocate resources for review.
   - Reviewers can also allocate their time better, since they will be able to recognize an APS with a higher percentage of pickup copy as a quicker task to complete.
     - Agency writers can understand that shorter writing tasks involving previously approved content are easier to fit into a busy schedule than a new writing project. PAAB reviewers work in a similar manner and can manage their schedules more effectively based on the % pickup and page # for the various APSs in their review queue.
3. **Pickup copy can be reviewed and accepted more easily.**
   - If pickup copy is not properly identified, reviewers may raise questions or comments on content that initially appears contentious but has been previously

approved based on acceptable clarification and/or evidence. This often results in agencies needing to cite backfiles in subsequent responses. Identifying pickup copy at the onset of review helps mitigate this back-and-forth.

- Please note that oversights may still occur, and reviewers may still raise comments on pickup copy if the review team deems it to be contentious upon further consideration.

For specific APS submission types: Reduced fee schedule and/or review times

- There are many features in the new fee schedule that cause APS comprised of a higher proportion of previously approved content to have a reduced fee versus similar APS with a lower proportion of previously approved content.
  - These features include:
    i. The criteria for applicability of series fees
    ii. Minor updates
    iii. APS with little new content (i.e. ≤2 new content pages). Note that this differs from "minor updates"
    iv. The incremental "per page of new content" component of the supplementary length fee.
- Clients who wish to benefit from the savings associated with previously approved components must participate in the shading process by clearly identifying the PAAB file number for each component that they desire to be credited as having been previously approved.

Benefits to fee schedule and review times*

Minor updates†	Renewals (100% pickup)†	APS with little new content (≤2 new pages)
Reduced base fees for standard submissions and ARO submissions No supplemental fees for >10 pages or >15 references	No supplemental fees for >10 pages or >15 references	AROs can be provided at the price of the immediately preceding urgency level (i.e., ARO-2 for the price of ARO-4, ARO-4 for the price of ARO-7, and so on)
Expedited review timeline **if** ARO is selected	Expedited review timeline **if** ARO is selected	Expedited review timeline **if** ARO is selected

* Please refer to the PAAB's fee schedule for more information about review fees.
† Please refer to the April 2022 Guidance on Submission Process and Format Requirements for more information on what qualifies as a renewal and as a minor update, and how these submissions can be done using layouts only (no copydecks).

Important note: If your company/agency chooses, they can forego the shading of pickup copy in copydecks and select 0% as the amount of pickup copy when submitting an APS. While we will accept submissions with 0% pickup at the full fee, we encourage utilizing the process to facilitate more timely review and to benefit from a potential fee reduction. Please note that PAAB must pursue revisions for code contraventions encountered during the analysis of a claim's evidentiary basis, even if the claim is later disclosed to have been previously approved.