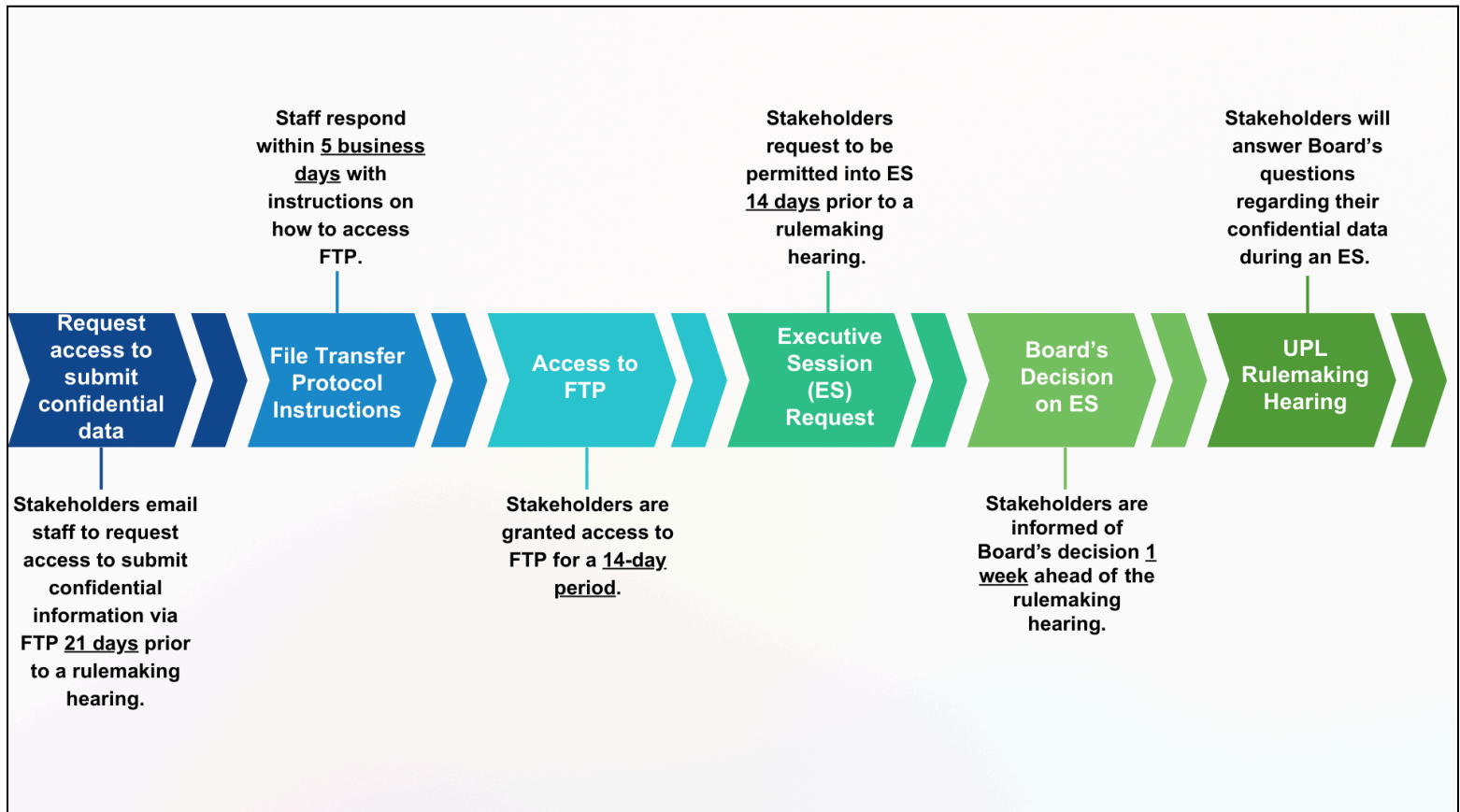




Confidential Information Submission Process

Purpose: This document is meant to provide guidance for stakeholders to submit **confidential information** to the Prescription Drug Affordability Board's (PDAB, the Board) consideration as part of a specific drug's upper payment limit (UPL) rulemaking. Details on submitting non-confidential data can be found in the data submission guide (DSG).

Timeline for Confidential Information Submission



Confidential Information Submission: File Transfer Protocol (FTP)

Information containing confidential, proprietary, or trade secret information must be submitted through a secure File Transfer Protocol (FTP). The request to submit confidential information via the FTP should be submitted at least **21 calendar days** prior to a rulemaking hearing. Stakeholders can request access by emailing staff at dora_ins_pdab@state.co.us. Staff will respond within **five business days** with full instructions on how to access the FTP and upload confidential information. In addition to uploading confidential information on the FTP, please include the following information in the body of the message:

- Name and contact information of the submitter
- Type of data being submitted



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- How the submission is relevant to the specific drug's UPL rulemaking hearing
- Attestation that the submission does not include dollars-per-quality adjusted life year (QALY), or similar measure that discounts the value of a life because of an individual's disability or age.

Please be aware that the FTP has a size limit of 1 GB, so larger amounts of data may need to be sent in multiple messages. **Access to the FTP can only be granted for a 14 day period**, so please do not start this process until you are ready to submit information to the Board. Confidential information must be submitted at least **14 calendar days** prior to the rulemaking hearing for it to be considered at the hearing. Any information submitted after that deadline will be considered at the following rulemaking hearing. The submitted information will be transmitted to the Board confidentially and will not be available to the public. The Board may deliberate the confidential information in executive session consistent with section 10-16-1404(3), C.R.S., and may invite the stakeholder into executive session as necessary to ask questions exclusively about the confidential information. More details on the Board's review of confidential information and executive session below.

Board Review and Executive Session

After stakeholders submit confidential information, staff will upload them to a secure folder that only staff, Board members, and Board attorneys can access. Stakeholders may request they be permitted into executive session to answer questions from the Board about the confidential information they submitted. The submitter must request to attend the executive session via an email to the staff at dora_ins_pdab@state.co.us **14 days** prior to a rulemaking hearing. The email request must include:

- The date of the rulemaking hearing stakeholder is requesting to speak at,
- Name and title of each stakeholder that will be participating in the executive session (if the stakeholder is different from the submitter),
- Attest no new information will be verbally discussed aside from what was initially submitted, and
- Attest any information including QALY will not be discussed.

Board staff will confirm receipt of the request within **3 business days**. The Board will decide whether or not a stakeholder is invited into the requested executive session. Stakeholders will be informed of the Board's decision via email **one week** ahead of the rulemaking hearing. The Board may reasonably limit the number of people answering questions related to confidential information during an executive session.

Consistent with Colorado open meetings requirements, the topic for discussion, including the stakeholder's name, will be noticed on the Board's meeting agenda and during the meeting before the Board enters executive session to discuss confidential information. An electronic record of the discussion held in the executive session will be made, and the record must be kept for at least 90 days following the executive session. The record is not available directly to the public for review and is not subject to discovery in any administrative or judicial proceeding.¹

¹ <https://dlg.colorado.gov/open-meetings-requirements>

Pursuant to Colorado Open Records laws, the Division denies the right of inspection to records that are trade secret, privileged information, and confidential commercial or financial information. Division policy is to contact any entity that labels a document as “confidential” to justify its confidentiality in the event of a CORA request. If discovery of confidential information is requested as part of future litigation, to the extent permitted, PDAB and staff will notify the entity that submitted the confidential information and seek protective orders as part of the litigation.