Washington State Health Care Authority

Manufacturer Data Submission Guide

Drug Price Transparency – RCW 43.71C
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Contents

About 2
Contacts 2
Compliance 2
Definitions 2
Submission Schedule 4
How to Register 5
How to Submit 5
    Resubmissions 5
Submission Specifications 5
    Data Validation 5
    File Specifications 6
    Data Specifications 6
Table Specifications 6
  New Covered Drugs and Qualifying Price Increases 6
  New Drug Application 15
Appendix A – ST Web Client User Guideline 18
Appendix B – SFT Client Options (Partial List) 28

About

In 2019, the Washington State Legislature passed a law (Chapter 43.71C RCW) which creates the Drug Price Transparency (DPT) program at Health Care Authority (HCA). The law requires issuers of health insurance, pharmacy benefit managers (PBMs), manufacturers, and pharmacy service administrative organizations (PSAOs), to submit data on drug costs and pricing to HCA, for the agency to create annual reports for the public and legislature synthesizing the data to demonstrate the overall impact that drug costs, rebates, and other discounts have on health care premiums.

You may visit HCA website for more information.

https://www.hca.wa.gov/about-hca/clinical-collaboration-and-initiatives/prescription-drug-cost-transparency

HCA developed this submission guide with input from stakeholders. This included a process which allowed for stakeholder review and comment on drafts of data definitions. HCA has final approval authority over the data submission guides and all subsequent changes.

For recent updates about the Drug Price Transparency (DPT) program, please see the link below:

https://www.hca.wa.gov/billers-providers-partners/prescription-drug-cost-transparency-update

Contacts

For any questions about the Drug Price Transparency program, please contact the program staff by sending an email:

drugtransparency@hca.wa.gov

Compliance

For information regarding compliance with the Drug Price Transparency program, please contact program staff by sending an email to:

drugtransparency@hca.wa.gov.

HCA has filed a CR101 to revise WAC 182-51-0600, to give manufacturers additional time to report information required on new covered drugs under RCW 43.71C.050. Until the rule is revised, HCA will not initiate enforcement under RCW 43.71C.090 for manufacturers who do not report the information required by RCW 43.71C.050 *prior* to release of a new covered drug to the market.

Definitions

"Authority" means the health care authority.

"Calendar days" means the same as in WAC 182-526-0010.

“Calendar year” means the period from January 1 to December 31 of each year.

"Covered drug" means any prescription drug that:

(a) A covered manufacturer intends to introduce to the market in Washington State at a wholesale acquisition cost of ten thousand dollars or more for a course of treatment lasting less than one month or a thirty-day supply, whichever period is longer; or

(b) Meets all of the following:

(i) Is currently on the market in Washington State;

(ii) Is manufactured by a covered manufacturer; and

(iii) Has a wholesale acquisition cost of more than one hundred dollars for a course of treatment lasting less than one month or a thirty-day supply, and, taking into account only price increases that take effect after July 28, 2019, the manufacturer increases the wholesale acquisition cost such that:

(A) The new wholesale acquisition cost is twenty percent higher than the wholesale acquisition cost on the same day of the month, twelve months before the date of the proposed increase; or

(B) The new wholesale acquisition cost is fifty percent higher than the wholesale acquisition cost on the same day of the month, thirty-six months before the date of the proposed increase.

"Covered manufacturer" means a person, corporation or other entity engaged in the manufacture of prescription drugs sold in or into Washington State. "Covered manufacturer" does not include a private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store label, or a prescription drug repackager.

"Data" means all data provided to the authority under RCW 43.71C.020 through 43.71C.080 and any analysis prepared by the authority.

"Data submission guide" means the document identifies the data required under RCW 43.71C, and provides instructions for submitting this data to the authority, including guidance on required format for reporting, for each reporting entity.

"Food and drug administration (FDA) approval date" means the deadline for the FDA to review applications for new drugs or new biologics after the new drug application or biologic application is accepted by the FDA as complete in accordance with the Prescription Drug User Fee Act of 1992 (106 Stat. 4491; P.L. 102-571).

"Introduced to market" means marketed in Washington State.

"Pipeline drug" means a drug or biologic product containing a new molecular entity, not yet approved by the Food and Drug Administration, for which a manufacturer intends to seek initial approval from the Food and Drug Administration under an original new drug application under 21 U.S.C. Sec. 355(b) or under a biologics license application under 42 U.S.C. Sec. 262 to be marketed in Washington State.

"Prescription drug" means a drug regulated under chapter 69.41 or 69.50 RCW, including generic, brand name, specialty drugs, and biological products that are prescribed for outpatient use and distributed in a retail setting.

"Rebate" means negotiated price concessions, discounts, however characterized, that accrue directly or indirectly to a reporting entity in connection with utilization of prescription drugs by reporting entity members including, but not limited to, rebates, administrative fees, market share rebates, price protection rebates, performance-based price concessions, volume-related rebates, other credits, and any other negotiated price concessions or discounts that are reasonably anticipated to be passed through to a reporting entity during a coverage year, and any other form of price concession prearranged with a covered manufacturer, dispensing pharmacy, pharmacy benefit manager, rebate aggregator, group purchasing organization, or other party which are paid to a reporting entity and are directly attributable to the utilization of certain drugs by reporting entity members.

"Reporting entity" means carriers, covered manufacturers, health carriers, health plans, pharmacy benefit managers, and pharmacy services administrative organizations, which are required to or voluntarily submit data according to chapter 43.71C RCW.

"Wholesale acquisition cost" means, with respect to a prescription drug, the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, excluding any discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale acquisition cost guides or other publications of prescription drug pricing.

Submission Schedule

The table below describes the schedule of submissions that are required for you to be in compliance with the DPT program. This includes both the initial submission at the start of the program, in October of 2020, and ongoing submissions on an annual basis.

Report Type	Submission Due Date	Description
New Covered Drugs and qualifying price increases	Beginning October 16, 2020	A covered manufacturer must submit to the authority all data specified in RCW 43.71C.050 and 43.71C.070, following the guidelines set forth in this data submission guide, for each newly marketed covered drug or a covered drug that had a qualifying price increase on or after October 16, 2020, as follows: (a) Sixty days in advance of a qualifying prices increase for a covered drug marketed in Washington State; or (b) Thirty days in advance of a new covered drug's introduction to market in Washington State.
	December 31, 2020	A covered manufacturer must submit to the authority all data specified in RCW 43.71C.050 and 43.71C.070, following the guidelines set forth in this data submission guide for each newly marketed covered drug, or a covered drug that had a qualifying price increase between and including October 1, 2019, and October 15, 2020
New Drug Application (notice from FDA that drug will be reviewed by deadline)	Beginning October 16, 2020	A manufacturer must submit to the authority all data specified in RCW 43.71C.060(1), following the guidelines set in the authority's applicable data submission guide for all new drug applications or biologic license applications for pipeline drugs submitted on or after October 16, 2020, within sixty calendar days of the manufacturer receiving the FDA approval date.
	December 31, 2020	A manufacturer must submit to the authority all data specified in RCW 43.71C.060(1), following the guidelines set forth in this data submission guide for all new drug applications or biologic license applications for pipeline drugs submitted on or after October 1, 2019, through October 15, 2020, for which the manufacturer has received an FDA approval date.

How to Register

In order to submit data to HCA, you must first complete the registration process and receive credentials to submit data through the Secure File Transfer (SFT) service offering hosted by Washington Technology Solutions (WATECH).

To register, you must complete and submit the registration form to HCA. You can access the form at the link below. Once you've completed the required information in the form, click the "Submit" button to generate an email. Registering thirty days in advance of a reporting due date for this program is strongly encouraged, in order to ensure ample time for you to be added to the system and given the ability to submit files by October 16, 2020.

https://www.hca.wa.gov/assets/billers-and-providers/13-0051-drug-price-transparency-submitter-registration.pdf

The form must be filled out completely. Incomplete submissions can cause delays in the registration process. Please see the contact email for any questions or concerns about the form and the registration process.

Once your registration is processed, you will be contacted by IT staff from HCA to establish your credentials to submit data to HCA.

How to Submit

To submit files for the Drug Price Transparency program, you will need to use the Secure File Transfer (SFT) service offering hosted by Washington Technology Solutions (WATECH), using the credentials provided to you by HCA. This will provide you with access to a personalized folder for your organization, where you can upload your submissions.

For more details on the process of connecting to SFT, and the tools that can be used to do so, please see "Appendix A – ST Web Client User Guideline" and "Appendix B – SFT Client Options (Partial List)".

There are checks in place to protect the SFT service which may result in the rejection of your submission, without notice. It is unlikely that you will ever trigger these protections, as the size and frequency of the submissions required for this program will never approach these limits. However, accidentally exceeding them could result in termination of your SFT credentials. These limits include (but are not limited to); any file uploaded above 30GB and an upload or download of 50,000 files or above in a 24-hour period. If you suspect that your SFT credentials are no longer working, please contact the DPT program staff.

Resubmissions

In the event that your submission is rejected, HCA will issue you a warning notice describing the reason your submission was rejected. Within 30 days after you receive the warning notice, you will need to resubmit the file after you have made the necessary corrections or request an extension of the due date. If you fail to comply with reporting requirements after receiving a warning notice, the authority may assess a fine.

To ensure that you receive credit for a resubmission, you should use the same YYYYMMDD value in the file name as you did in your first submission. For example, if you submitted the file 'manufacturer_covered_drugs_M12345_20201001.csv`, and received a rejection, after making corrections you should resubmit the file with the same name as it was originally submitted under, even if the date of resubmission is January 1, 2021.

Submission Specifications

Data Validation

Every submitted file is checked by automated and manual processes to ensure that the data meets the requirements of RCW 43.71C and is compatible with HCAs reporting software. The automated processes are applied shortly after submission and ensure that the data meet all of the technical rules described in the Table Specifications. These primarily cover checks of data types (number vs. string) and formats (2020-01-01 vs. 01/01/2020). The manual processes are performed by program staff after submission, and include more robust checks of the data for validity.

These validations may result in the rejection of your file submission. In the case of an automatic validation failure, the system will send an automated email to the email address registered for your organization. The automated email provides an error log detailing the reason for rejection. In the case of a manual validation failure, program staff will send an email explaining the reason for the rejection. In both cases, you will be required to resubmit your file after making the appropriate corrections. If you need help understanding your error log, the **Data Submission FAQ** clarifies the meaning of the error and provides guidance on how to correct the error.

If your submission passes the automated validation, you will receive an email confirming this at the registered email address for your organization. If you do not receive an automated notification of either success or failure within 72 hours, please contact DPT program staff at drugtransparency@hca.wa.gov for confirmation that your submission was received, and processed.

File Specifications

All files submitted must be text files with comma-separated values (CSV). The text should be encoded using the UTF-8 standard. Line endings in UNIX ("\n") or Windows ("\r\n") format are both acceptable. The header row must be included in every file. For detailed technical guidance, see the Library of Congress CSV Definition.

Appropriately formatted files can also be generated via Microsoft Excel by saving a spreadsheet in CSV format. This will remove many of the features included in Excel, such as formatting, formulas, and "sheets", so you may want to save a copy in Excel format for your own reference in the future.

File names should follow the naming scheme specified for the specific data that you are submitting. See the Table Specifications section for more information.

Data Specifications

Nullable: All fields are required, unless otherwise indicated in the table specification. If a field is not required, that will be indicated with the word "Nullable" in the specification. In those cases, you must leave that field blank, do not provide the value as "NULL", or otherwise provide a special indicator of a null value. In all other cases, providing a blank value will result in a rejection by the automated validation.

Date Formats: unless otherwise specified, all dates should be reported in ISO-8601 format with hyphens between years, months and days: "YYYY-MM-DD". For example, Nov. 1st, 2020 would be recorded as "2020-11-01".

Important note about Excel version: We recommend using Microsoft Excel 2016 or earlier for the submission guide templates. Using Microsoft Excel 2019 can cause formatting issues when saving as a CSV file and result in the file being rejected.

Table Specifications

New Covered Drugs and Qualifying Price Increases

This linked template contains all of the fields necessary to comply with the notification of a price increase and covered drug as described in RCW 43.71C.050 and 43.71C.070. Files submitted for manufacturer covered drugs should be named using the following schema, where ID is the manufacturer ID assigned to you by HCA during the registration process (Washington DPT Number), and YYYYMMDD is a placeholder for the submission date. In the case of a resubmission after file rejection, please use the same value for YYYYMMDD as the file that was rejected. Do not replace "manufacturer" with your organizations name, this will result in your submission being rejected.

File naming schema: manufacturer_covered_drugs_{ID}_{YYYYMMDD}.csv

Example: manufacturer_covered_drugs_M12345_20201016.csv

Please see the Submission Schedule for details regarding the timelines for submitting reports for covered drugs.

Specification	Description
Name: Washington DPT Number Type: String Max Length: 6 characters Format: ABCDE	WA Drug Price Transparency (DPT) assigned unique submitter identifier upon registration with the Health Care Authority Drug Price Transparency program. This number is unique to you and follows a format of either CXXXXX, MXXXXX, SXXXXX or PXXXXX where C, M, S and P indicate whether you are a carrier, manufacturer, PSAO or PBM. The X's are numeric digits e.g. 12345.
Name: Manufacturer Name Type: String Max Length: 80 characters Format: ABCDE	Labeler name of entity who markets the drug. This entity has the corresponding Labeler Code in the following data field.
Name: Labeler Code Type: Numeric Format: 00000 Max Length: 5 digits	Labeler code as assigned by Food and Drug Administration (FDA) These 5 digits should match the first 5 digits of all submitted NDCs in this report.
Name: Manufacturer ID Number Type: Numeric Format: 000000000 Max Length: 9 digits	ID number submitted by the manufacturer for which we can identify them. **EIN:** Federal US Tax ID number **DUNS:** Data Universal Numbering System is a 9 digit ID number assigned by Dun & Bradstreet **UBI:** Washington State Unique Business ID number **OTHER:** For entities without an EIN, DUNS, or UBI number; fill with zeros. **NOTE: Do not input special characters, or hyphens.**
Name: Manufacturer ID Type Type: Choice Choices: EIN,UBI,DUNS, OTHER	The type of ID that was submitted in the manufacturer ID number field. **EIN:** Federal US Tax ID number **DUNS:** Data Universal Numbering System is a 9 digit ID number assigned by Dun & Bradstreet **UBI:** Washington State Unique Business ID number **OTHER:** For entities without an EIN, DUNS, or UBI number.
Name: NDC Type: Numeric Format: 00000000000 Max Length: 11 digits Min Length: 11 digits	A three-segment code maintained by the Federal Food and Drug Administration that includes a labeler code, a product code, and a package code for a drug product (e.g. 12345678910) **NOTE: The NDC field must be eleven digits long and maintain leading zeros**.
Name: Chemical/Biochemical/Blood Product Name Type: String Max Length: 80 characters Format: ABCDE	Ingredient name including the salt form if any, without any other modifying elements, to be used as a grouper. For example, "fluoxetine" and "fluoxetine HCL" is acceptable. "Fluoxetine DR," "fluoxetine 20 mg tablets" are unacceptable for this field.
Name: Ingredient Name Type: String Max Length: 80 characters Format: ABCDE	Ingredient name, may include salt form, dosage form, strength, and any other information. For example, "fluoxetine 20 mg tablets" is acceptable. "fluoxetine", "fluoxetine HCL", "fluoxetine DR, are unacceptable for this field.

Name: Label Name Type: String Max Length: 80 characters Format: ABCDE	Proprietary or legal name as marketed by manufacturer. For example, "fluoxetine HCL", "fluoxetine DR, are acceptable. This field should not include strength or dosage form. If unknown insert the name used to identify the drug in the clinical trials.
Name: Drug Type Type: Choice Choices: S,N,I	Drug Type is one of following values: **Single Source (S)** – Drugs having an FDA New Drug Application (NDA), or biologics having a Biologics License Application (BLA), and for drugs, there are no generic alternatives available on the market. **Non-Innovator Multiple-Source (N)** – Drugs that have an FDA Abbreviated New Drug Application (ANDA). **Innovator Multiple-Source (I)** – Drugs which have an NDA and no longer have patent exclusivity.
Name: Unit of Measure Type: Choice Choices: AHF,CAP,SUP,GM,ML,TAB,TDP,EA	Unit of Measure for Wholesale Acquisition Cost (WAC) defined as one of the following values: **AHF**: Anti-hemophilia factor **CAP**: Capsule **SUP**: Suppository **GM**: Gram **ML**: Milliliter **TAB**: Tablet **TDP**: Transdermal patch **EA**: Each
Name: WAC - Current Type: Numeric Format: 999999999.99999 Max Length: 14 digits Nullable	The wholesale acquisition cost per unit of measure on the date of the submission (60 days prior to the effective date of the WAC increase). If the covered drug report is for a drug being introduced to the market, then leave blank. **NOTE: Do not include the dollar sign or commas.**
Name: WAC Effective Date Type: Date Format: YYYY-MM-DD Min Year: 1900 Max Year: 2100	Effective date of the wholesale acquisition cost increase for the drug product. If the covered drug report is for a new covered drug being introduced to the market, then this field should be the date the product will first be available.
Name: WAC Increase Type: Numeric Format: 999999.99999 Max Length: 11 digits Nullable Rule: Greater than zero when “Qualifying Price Increase" is equal to Y.	Amount of wholesale acquisition cost increase per unit of measure for the drug product. Express this as a dollar amount up to 5 decimal places. If the covered drug report is for a new drug being introduced to the market, leave blank. **NOTE: Do not include the dollar sign or commas.**
Name: WAC - New Type: Numeric Format: 999999999.99999 Max Length: 14 digits Rule: greater than 0	The new wholesale acquisition cost (WAC) per unit of measure on the WAC effective date. If the covered drug report is for a new covered drug being introduced to the market, then this field should be the WAC on the date the product is first available. **NOTE: Do not include the dollar sign or commas.**

Name: Existing Manufacturer Drug Type: Choice Choices: Y,N	Mark “Y” if the drug has been manufactured by the manufacturer for the previous 5 years. If “Y”, the WAC for the previous 5 years must be reported. Mark “N” if the drug has been manufactured by the manufacturer for less than 5 year. The WAC for the previous 5 years is not required.
Name: WAC - 1 Year Prior Type: Numeric Format: 999999999.99999 Max Length: 14 digits Nullable Rule: Greater than zero when column "Existing Manufacturer Drug" is equal to Y	Wholesale acquisition cost per unit of measure 12 months prior to WAC Effective Date. This field must be populated if you have manufactured this drug for 5 or more years. **NOTE: Do not include the dollar sign or commas.**
Name: WAC - 2 Year Prior Type: Numeric Format: 999999999.99999 Max Length: 14 digits Nullable Rule: Greater than zero when column "Existing Manufacturer Drug" is equal to Y	Wholesale acquisition cost per unit of measure 24 months prior to WAC Effective Date. This field must be populated if you have manufactured this drug for 5 or more years. **NOTE: Do not include the dollar sign or commas.**
Name: WAC - 3 Year Prior Type: Numeric Format: 999999999.99999 Max Length: 14 digits Nullable Rule: value is populated when column "Existing Manufacturer Drug" is equal to Y	Wholesale acquisition cost per unit of measure 36 months prior to WAC Effective Date. This field must be populated if you have manufactured this drug for 5 or more years. **NOTE: Do not include the dollar sign or commas.**
Name: WAC - 4 Year Prior Type: Numeric Format: 999999999.99999 Max Length: 14 digits Nullable Rule: value is populated when column "Existing Manufacturer Drug" is equal to Y	Wholesale acquisition cost per unit of measure 48 months prior to WAC Effective Date. This field must be populated if you have manufactured this drug for 5 or more years. **NOTE: Do not include the dollar sign or commas.**
Name: WAC - 5 Year Prior Type: Numeric Format: 999999999.99999 Max Length: 14 digits Nullable Rule: value is populated when column "Existing Manufacturer Drug" is equal to Y	Wholesale acquisition cost per unit of measure 60 months prior to WAC Effective Date. This field must be populated if you have manufactured this drug for 5 or more years. **NOTE: Do not include the dollar sign or commas.**
Name: Qualifying Price Increase Type: Choice Choices: Y,N	Indicator for qualifying price increase. Manufacturer must use this field as 'yes' or 'no' to indicate if the drug meets the criteria of a qualifying price increase as defined in RCW 43.71C.010(8).

Name: Change/Improvement Description Type: String Max Length: 5000 characters Format: ABCDE Rule: value is populated when column "Qualifying Price Increase" is equal to Y	A narrative description of any change or improvement in the drug that necessitates the WAC increase.
Name: Financial Factors Type: String Max Length: 5000 characters Format: ABCDE	A narrative description of the specific financial factors used to make the decision to set the WAC for a new Covered Drug or to increase the wholesale acquisition cost of an existing Covered Drug.
Name: Non-financial factors Type: String Max Length: 5000 characters Format: ABCDE	A narrative description of the specific non-financial used to make the decision to set the WAC for a new Covered Drug or to increase the wholesale acquisition cost of an existing Covered.
Name: Patent Expiration Date Type: Date Format: YYYY-MM-DD Min Year: 1900 Max Year: 2100 Nullable	The date when all patents on the drug product will expire. Patents owned by the manufacturer (i.e. originator or the inventor). Blanks are acceptable.
Name: Market Entry Date Type: Date Format: YYYY-MM-DD Min Year: 1900 Max Year: 2100	The date the drug was made available for purchase in Washington state.
Name: WAC - Market Entry Type: Numeric Format: 999999999.99999 Max Length: 14 digits Nullable	The wholesale acquisition cost per unit of measure for the existing Covered Drug on the Market Entry Date of that Covered Drug. For new to market Covered Drugs, leave blank. **NOTE: Do not include the dollar sign or commas.**
Name: Reporting Period From Type: Date Format: YYYY-MM-DD Min Year: 1900 Max Year: 2100 Nullable	The starting date of the period being used to report for annual manufacturing, marketing and advertising costs. Report the most recent completed calendar year. For example, if the effective date of the WAC increase is January 1, 2021 through February 28, 2021, report calendar year 2019. If the effective date of the WAC increase is March 1, 2021 through December 31, 2021, report calendar year 2020.
Name: Reporting Period To Type: Date Format: YYYY-MM-DD Min Year: 1900 Max Year: 2100 Nullable	The ending date of the period being used to report for annual manufacturing, marketing and advertising costs. Report the most recent completed calendar year. For example, if the effective date of the WAC increase is January 1, 2021 through February 28, 2021, report calendar year 2019. If the effective date of the WAC increase is March 1, 2021 through December 31, 2021, report calendar year 2020.

Name: Manufacturing Costs Type: Numeric Format: 999999999999999.99 Max Length: 17 digits	The total cost to produce the number of units manufactured in most recent completed calendar year prior to the WAC Effective Date. For example, if the effective date of the WAC increase is January 1, 2021 through February 28, 2021, report calendar year 2019, if the WAC Effective Date is March 1, 2020 through December 31, 2021 report the total cost to manufacture the drug product in calendar year 2020. For new to market covered drugs, fill with zeros. **NOTE: Do not include the dollar sign or commas.**
Name: Marketing and Advertising Costs Type: Numeric Format: 999999999999999.99 Max Length: 17 digits Nullable	Amount spent on marketing and advertising, in the most recent completed calendar year prior to the WAC Effective Date, including but not limited to direct to consumer marketing (television, radio print, digital, etc.), salaries for sales representatives, salaries for medical liaisons, hosted CE events and provider education, and provider detailing. For example, if the effective date of the WAC increase is between and including January 1, 2021 through February 28, 2021, report calendar year 2019. If the effective date of the WAC increase is between and including March 1, 2021 through December 31, 2021, report calendar year 2020. For new to market covered drugs, leave blank. **NOTE: Do not include the dollar sign or commas.**
Name: Clinical Trials Costs Type: Numeric Format: 999999999999999.99 Max Length: 17 digits	Total costs for all clinical trials for the covered drug. **NOTE: Do not include the dollar sign or commas.**
Name: Research and Development Cost Type: Numeric Format: 999999999999999.99 Max Length: 17 digits	Total expenditure on research and development prior to Market Entry Date. **NOTE: Do not include the dollar sign or commas.**
Name: Regulation Costs Type: Numeric Format: 999999999999999.99 Max Length: 17 digits	All costs paid by the manufacturer to the FDA and any other regulatory body for considering their drug application and bringing the drug to market. **NOTE: Do not include the dollar sign or commas.**
Name: Acquired from Previous Manufacturer Type: Choice Choices: Y,N	Indicator for whether the drug was acquired from another manufacturer in the previous 5 years. Manufacturer must use this field as 'yes' or 'no' to indicate if the drug meets the criteria in RCW 43.71C.050(4)?
Name: Previous Owner's Name Type: String Max Length: 80 characters Format: ABCDE Nullable Rule: value is populated when column "Acquired from Previous Manufacturer" is equal to Y	The legal name of entity who sold the covered drug to the manufacturer.

Name: Previous Manufacturer ID Type: Numeric Format: 00000 Max Length: 5 digits Nullable Rule: value is populated when column "Acquired from Previous Manufacturer" is equal to Y	If the drug product was purchased from another manufacturer, repackager, or private label distributor, the labeler code as assigned by Food and Drug Administration (FDA). If previous owner does not have a labeler ID fill with 5 zeros.
Name: Previous NDC Type: Numeric Format: 00000000000 Max Length: 11 digits Min Length: 11 digits Nullable Rule: value is populated when column "Acquired from Previous Manufacturer" is equal to Y	The NDC that was used by the original or previous manufacturer. For new drug products that do not have a previous NDC fill with eleven zeros. **NOTE: The NDC field must be eleven digits long and maintain leading zeros.**
Name: Purchase Price Type: Numeric Format: 999999999999999.99 Max Length: 17 digits Nullable Rule: value is populated when column "Acquired from Previous Manufacturer" is equal to Y	If the drug product was not developed by the manufacturer, the amount the manufacturer paid to acquire the drug. **NOTE: Do not include the dollar sign or commas.**
Name: Currency of Purchase Type: String Max Length: 50 characters Format: ABCDE Nullable Rule: value is populated when column "Acquired from Previous Manufacturer" is equal to Y	The country of acquisition and type currency used to acquire the drug e.g. USD, EUR, GBP, CAD, JPY, AUD, INR, CNY, MXN, etc.
Name: Acquisition Date Type: Date Format: YYYY-MM-DD Min Year: 1900 Max Year: 2100 Nullable Rule: value is populated when column "Acquired from Previous Manufacturer" is equal to Y	If the drug product was not developed by the manufacturer, the date the manufacturer acquired the drug.
Name: WAC - Acquisition Type: Numeric Format: 999999999.99999 Max Length: 14 digits Nullable Rule: value is populated when column "Acquired from Previous Manufacturer" is equal to Y	The wholesale acquisition cost per unit of measure for the drug product on the acquisition date. **NOTE: Do not include the dollar sign or commas.**

Name: WAC - Prior to Acquisition Type: Numeric Format: 999999999.99999 Max Length: 14 digits Nullable Rule: value is populated when column "Acquired from Previous Manufacturer" is equal to Y	The wholesale acquisition cost per unit of measure for the drug product 12 months prior to the acquisition date. **NOTE: Do not include the dollar sign or commas.**
Name: Unit of Measure – Prior to Acquisition Type: Choice Choices: AHF,CAP,SUP,GM,ML,TAB,TDP,EA Nullable Rule: value is populated when column "WAC – Prior to Acquisition" is equal to any non-zero value	Unit of Measure for WAC (prior to acquisition) defined as one of the following values: **AHF**: Anti-hemophilia factor **CAP**: Capsule **SUP**: Suppository **GM**: Gram **ML**: Milliliter **TAB**: Tablet **TDP**: Transdermal patch **EA**: Each
Name: Financial Assistance Program Costs Type: Numeric Format: 999999999999999.99 Max Length: 17 digits Rule: greater than or equal to 0	Total cost of all financial assistance programs including financial assistance for uninsured individuals, compassionate use, patient assistance, charity care, donated drug product, etc., associated with the drug product for the calendar year prior to the WAC Effective Date. For example if the WAC Effective Date is March 1, 2020 report the total amount spent on financial assistance programs in calendar year 2019. If no financial assistance was provided fill with zeros. **NOTE: Do not include the dollar sign or commas.**
Name: Rebates Type: Numeric Format: 999999999999999.99 Max Length: 17 digits Rule: greater than or equal to 0	Total amount of rebates paid out associated with the NDC in the calendar year prior to the WAC Effective Date. For example if the WAC Effective Date is March 1, 2020 report the total amount of rebates paid to any entity in calendar year 2019. If no rebates were provided fill with zeros. **NOTE: Do not include the dollar sign or commas.**
Name: Cost Share Assistance Type: Numeric Format: 999999999999999.99 Max Length: 17 digits Rule: greater than or equal to 0	Total amount of money paid toward lowering an insured individual's out of pocket expenditure for the drug product in the calendar year prior to the WAC Effective Date. For example if the WAC Effective Date is March 1, 2020 report the total amount spent on cost share assistance in calendar year 2019. If no financial assistance was provided fill with zeros. **NOTE: Do not include the dollar sign or commas.**
Name: Other Financial Assistance Amount Type: Numeric Format: 999999999999999.99 Max Length: 17 digits Rule: greater than or equal to 0	Total amount of all other financial assistance paid out associated with the NDC in the calendar year prior to the WAC Effective Date. For example if the WAC Effective Date is March 1, 2020 report the total amount of all other financial assistance paid to any entity in calendar year 2019. If no other financial assistance was provided fill with zeros. **NOTE: Do not include the dollar sign or commas.**
Name: General Comments Type: String Format: ABCDE Max Length: 9999 characters Nullable	This field is intended for any clarifying statements or comments for any of the fields reported in this submission. If there are no statements or comments, this field may be left blank.

New Drug Application

This report contains all of the data fields necessary to comply with reporting a New Drug Application to HCA, per RCW 43.71C.060.

Files submitted for manufacturer new drugs should be named using the following schema, where: ID is the manufacturer ID assigned to you by HCA during the registration process (Washington DPT Number), and YYYYMMDD is a placeholder for the submission date. In the case of a resubmission after file rejection, please use the same value for YYYYMMDD as the file that was rejected. Do not replace "manufacturer" with your organizations name, this will result in your submission being rejected.

File naming schema: `manufacturer_new_drugs_{ID}_{YYYYMMDD}.csv`

`Example: manufacturer_new_drugs_M12345_20201005.csv`

Please see the Submission Schedule for details regarding the timelines for submitting reports for covered drugs.

Specification	Description
Name: Washington DPT Number Type: String Max Length: 6 characters Format: ABCDE	WA Drug Price Transparency (DPT) assigned unique submitter identifier upon registration with the Health Care Authority Drug Price Transparency program. This number is unique to you and follows a format of either CXXXXX, MXXXXX, SXXXXX or PXXXXX where C, M, S and P indicate whether you are a carrier, manufacturer, PSAO or PBM. The X's are numeric digits e.g. 12345.
Name: Manufacturer Name Type: String Max Length: 80 characters Format: ABCDE	Labeler name of entity who manufactures and markets the drug.
Name: Labeler Code Type: Numeric Format: 00000 Max Length: 5 digits	Labeler code as assigned by Food and Drug Administration (FDA)
Name: Manufacturer ID Number Type: Numeric Format: 000000000 Max Length: 9 digits	ID number submitted by the manufacturer for which we can identify them. **EIN:** Federal US Tax ID number **DUNS:** Data Universal Numbering System is a 9 digit ID number assigned by Dun & Bradstreet **UBI:** Washington State Unique Business ID number **OTHER:** For entities without an EIN, DUNS, or UBI number; fill with zeros. **NOTE: Do not insert special characters or hyphens.**
Name: Manufacturer ID Type Type: Choice Choices: EIN,UBI,DUNS, OTHER	The type of ID that was submitted in the manufacturer ID number field. **EIN:** Federal US Tax ID number **DUNS:** Data Universal Numbering System is a 9 digit ID number assigned by Dun & Bradstreet **UBI:** Washington State Unique Business ID number **OTHER:** For entities without an EIN, DUNS, or UBI number.

Name: Chemical/Biochemical/Blood Product Name Type: String Max Length: 80 characters Format: ABCDE	Ingredient name including salt form, without any other modifying elements, to be used as a grouper. For example, "fluoxetine" and "fluoxetine HCL", is acceptable. "Fluoxetine DR," "fluoxetine 20 mg tablets" are unacceptable for this field.
Name: Ingredient Name Type: String Max Length: 80 characters Format: ABCDE	Ingredient name, may include salt form, dosage form, strength, and any other information. For example, "fluoxetine 20 mg tablets" is acceptable. "fluoxetine", "fluoxetine HCL", "fluoxetine DR, are unacceptable for this field
Name: Label Name Type: String Max Length: 80 characters Format: ABCDE	Proprietary or legal name as marketed by manufacturer. For example, “Prozac”, "fluoxetine HCL", "fluoxetine DR, are acceptable.
Name: Drug Type Type: Choice Choices: S,N,I	Drug Type is one of following values: **Single Source (S)** – Drugs having an FDA New Drug Application (NDA), or biologics having a Biologics License Application (BLA), and there are no generic alternatives available on the market. **Non-Innovator Multiple-Source (N)** – Drugs that have an FDA Abbreviated New Drug Application (ANDA). **Innovator Multiple-Source (I)** – Drugs which have an NDA and no longer have patent exclusivity.
Name: Application Type Type: Choice Choices: BLA,NDA	Application Type is one of following values: **New Drug Application (NDA)** – Drug is a pipeline drug and was submitted as a New Drug Application to the FDA. **Biologics License Application (BLA)** – Drugs is a pipeline drug and was submitted as a Biologics License Application to the FDA.
Name: Regulatory Pathway Type: Choice Choices: 505(b)(1), 351(a)	Regulatory pathway for approval by the Food and Drug Administration. Acceptable values are 505(b)(1) or 351(a).
Name: Application Number Type: Numeric Format: 000000 Max Length: 6 digits Min Length: 6 digits	The application number assigned by the Food and Drug Administration. For application numbers less than 6 digits, the application number should be preceded using zeros.
Name: Application Supplement Number Type: Numeric Format: 0000 Max Length: 4 digits Min Length: 4 digits	The supplemental application number assigned by the Food and Drug Administration. For application numbers less than 4 digits, the supplemental application number should be preceded using zeros.

Name: Significant Impact on State Expenditures Type: Choice Choices: Y,N	Indicator of whether the pipeline drug will cost Washington State government agencies at least $50,000 per biennium in any future biennium. HCA believes that drugs costing at least $50,000 per biennium for Washington State government agencies to qualify as a significant impact on state expenditures. HCA may request from the manufacturer the information in the remaining fields if HCA believes the drug will have a significant impact on state expenditures and require manufacturers to resubmit with information for all of the following fields. If manufacturers believe drugs to meet or exceed this threshold, the following fields may be completed.
Name: Proposed Indication Type: String Max Length: 5000 characters Format: ABCDE Nullable	The proposed indication or indications submitted on the application to the FDA. Use the SNOMED CT disease term listed on the application. Use a semi-colon to separate multiple indications. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: Area of Study Type: String Max Length: 5000 characters Format: ABCDE Nullable	A list of diseases, conditions, and therapeutic areas being studied for this drug and whether the chemical drug has received an indication in the FDA approved labeling for use in these diseases, conditions, or therapeutic areas. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: Route of Administration Type: String Max Length: 5000 characters Format: ABCDE Nullable	List each route of administration being studied for this drug, including any differences between immediate-release and extended-release formulations. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: Clinical Comparator Type: String Max Length: 5000 characters Format: ABCDE Nullable	All clinical comparators including dosage regimen being used for which to evaluate the comparative differences in safety, efficacy, effectiveness, costs, value, or any other outcomes in clinical trials. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: PDUFA Date Type: Date Format: YYYY-MM-DD Min Year: 1900 Max Year: 2100 Nullable	Prescription Drug User Fee Act (PDUFA) date assigned by the FDA. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: Rare Disease Indication Type: Choice Choices: Y,N Nullable	Indicator of whether the FDA assigned the drug as being defined as a treatment for a rare disease. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: Orphan Drug Status Type: Choice Choices: Y,N Nullable	Indicator of whether the FDA assigned the drug as having an Orphan designation. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.

Name: Orphan Designation Number Type: Numeric Format: 000000 Max Length: 6 digits Min Length: 6 digits Nullable	Orphan designation number assigned by the FDA. For Orphan Designation numbers less than 6 digits, the supplemental application number should be preceded using zeros. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: Pediatric Indication Type: Choice Choices: Y,N Nullable	Indicator of whether the indication is for use in individuals under 18 years of age. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: Fast Track Status Type: Choice Choices: Y,N Nullable	Indicator of whether the FDA assigned the drug as having fast track status. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: Breakthrough Therapy Status Type: Choice Choices: Y,N Nullable	Indicator of whether the FDA assigned the drug as having breakthrough therapy status. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: Accelerated Approval Status Type: Choice Choices: Y,N Nullable	Indicator of whether the FDA assigned the drug as having accelerated approval status. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: Priority Review Status Type: Choice Choices: Y,N Nullable	Indicator of whether the FDA assigned the drug as having priority review status. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: New Molecular Entity Status Type: Choice Choices: Y,N Nullable	Indicator of whether the FDA assigned the drug as having new molecular entity status. Manufacturers may submit this information voluntarily if the pipeline drug is expected to cost Washington State at least $50,000 per year.
Name: General Comments Type: String Format: ABCDE Max Length: 9999 characters Nullable	This field is intended for any clarifying statements or comments for any of the fields reported in this submission. If there are no statements or comments, this field may be left blank.

Appendix A – ST Web Client User Guideline

Prerequisites

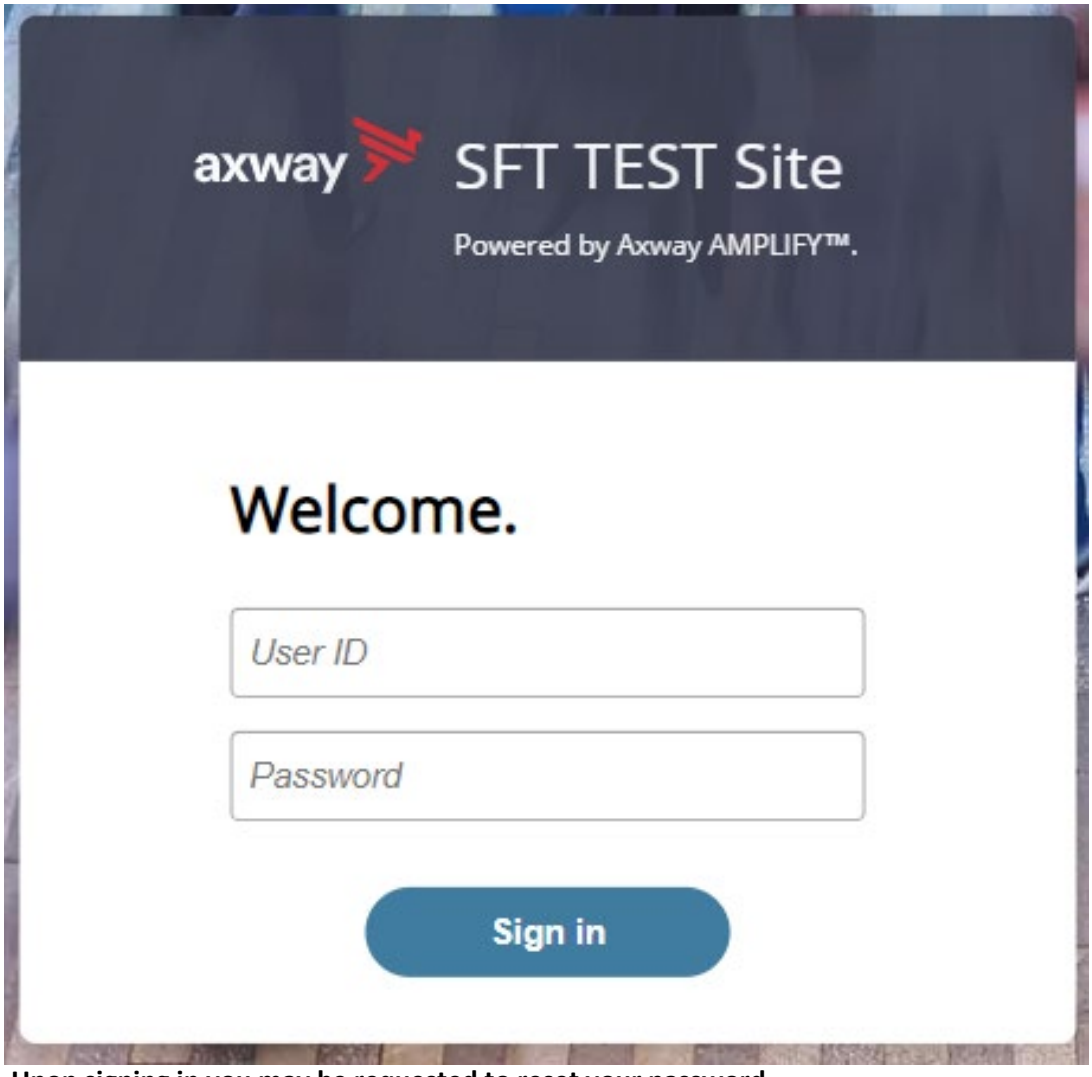
Before you can log in to ST Web Client and open a session, you need:

- A high-speed Internet connection
- A supported Internet browser:
    - Microsoft Internet Explorer 11
    - Microsoft Edge - latest version
    - Mozilla Firefox - latest version
    - Apple Safari - latest version
    - Google Chrome - latest version
- A connection URL to paste into your browser: https://sft.wa.gov or https://sft-test.wa.gov
- A user name and password. This information is provided to you by State of Washington business partner. You must enter this information on the Log in page.

Sign in with your password

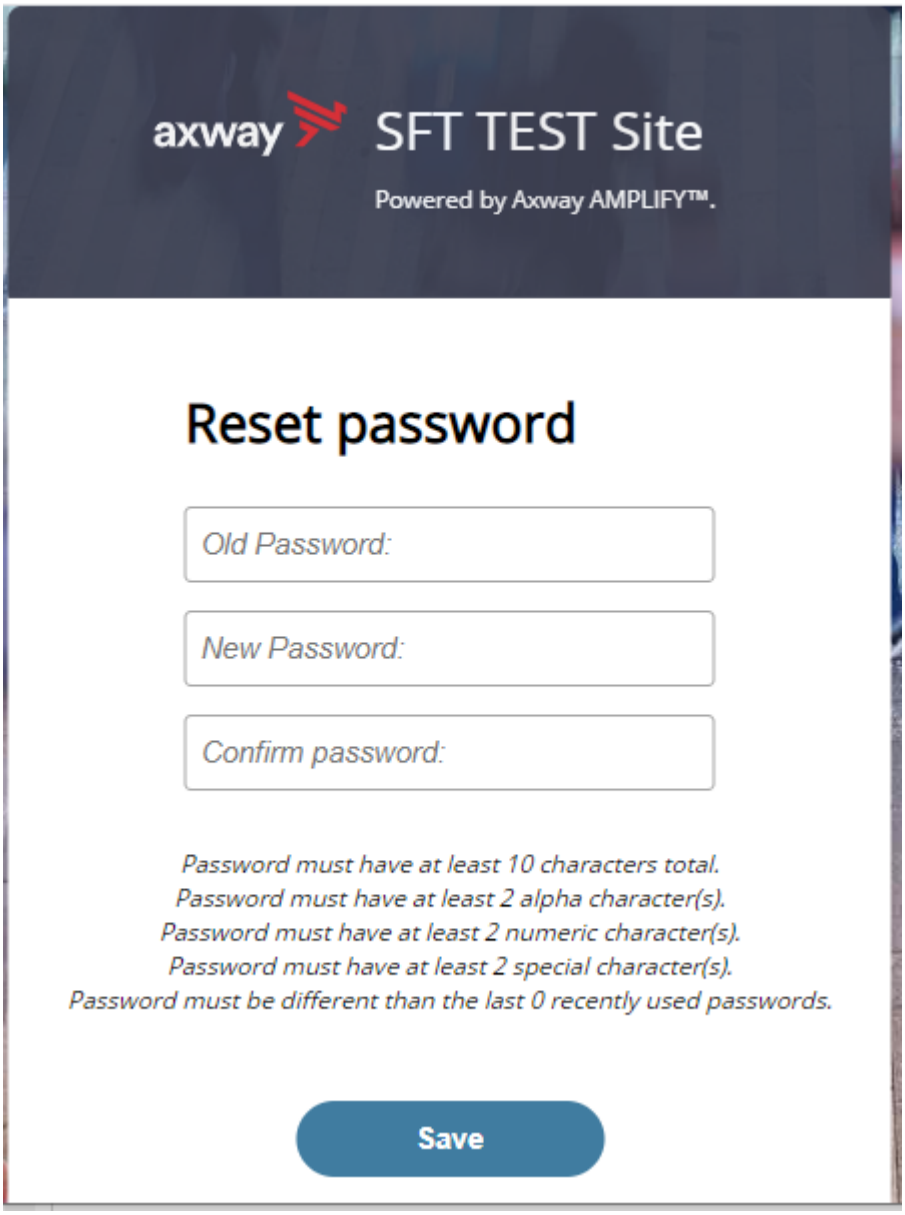
To sign into ST Web Client:

1. Open a supported browser. Use this URL for Production Site - https://sft.wa.gov
2. Enter the connection URL and press enter. This Sign in page should be displayed.



Upon signing in you may be requested to reset your password

This required when a temporary password was given to you.



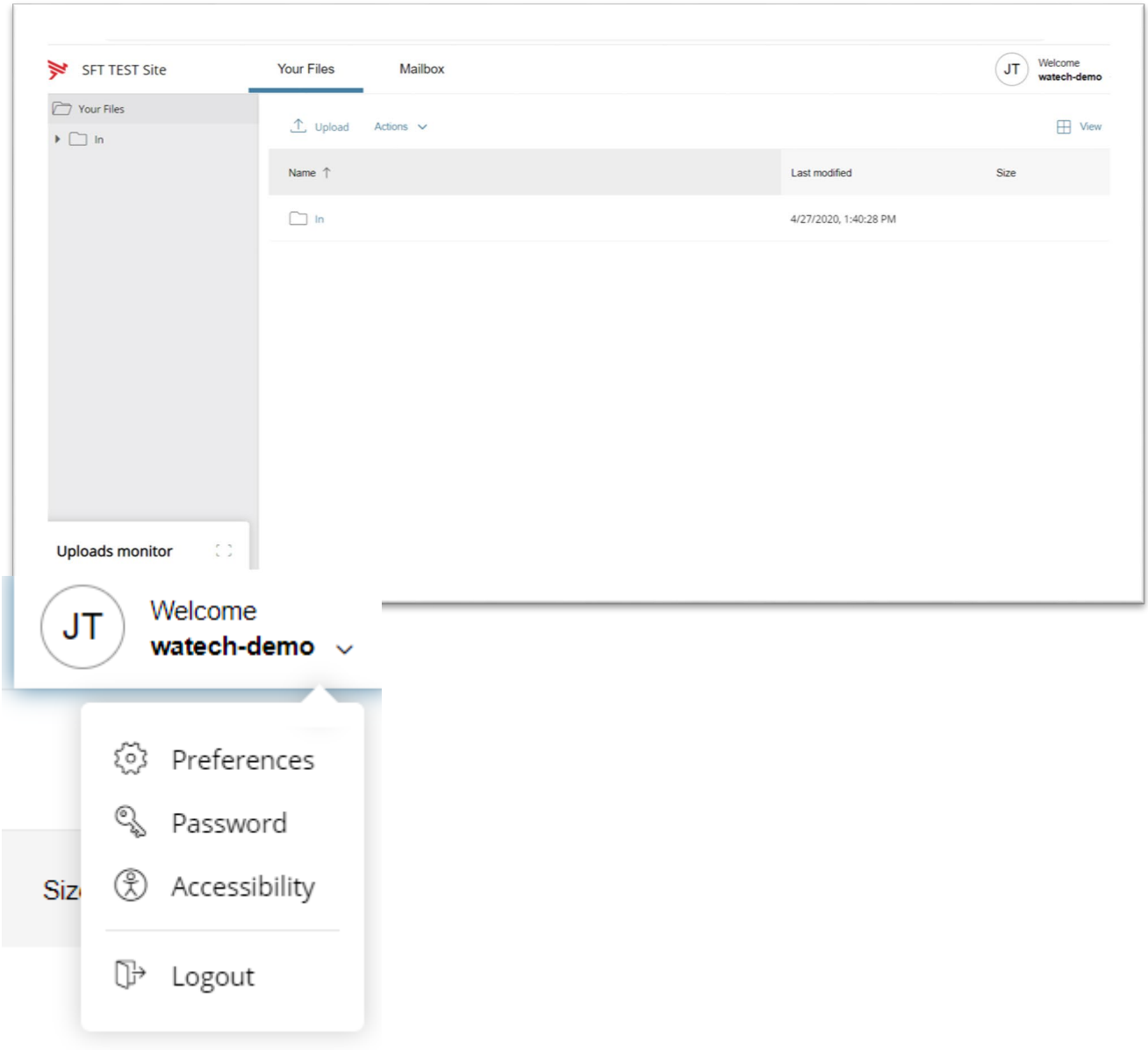
Change password page is displayed as above.

If you attempt to sign in and you receive a message that indicates you must reset your password, follow these steps:

1. Enter your old password or the temporary password provided by the system administrator.
2. Enter your new password. Your new password must meet the listed criteria defined by Office of Cyber Security State of Washington.
3. Confirm your new password.
4. Click **Save**.

Main page in ST Web Client

This page is displayed after successful login.



Welcome menu

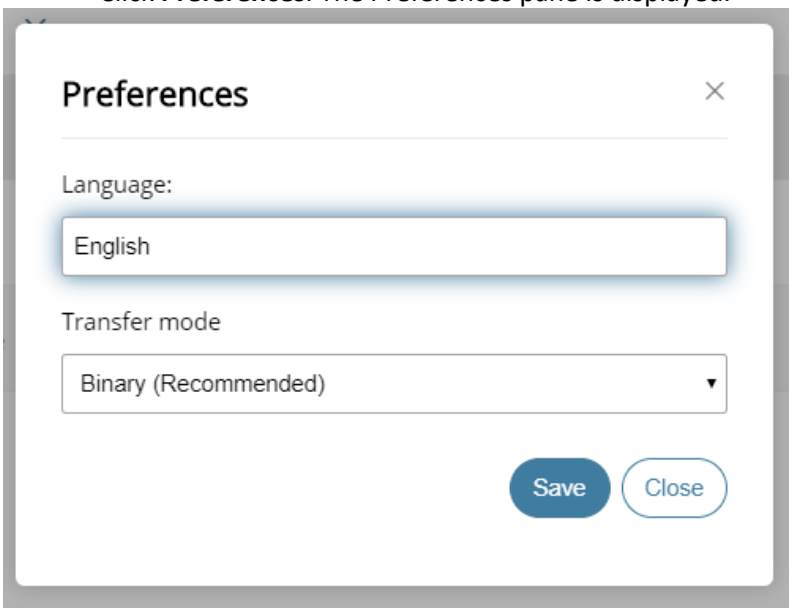
Using the Welcome menu (drop down menu on the upper right corner of page), you can access the tools to manage your user profile as well as logout.

- Log out
- Select the **Welcome** drop-down.
- Click **Logout**.

Set preferences

To set a preference:

- Select the **Welcome** drop-down.
- Click **Preferences**. The Preferences pane is displayed.



Select a Transfer mode

The recommended and default Transfer mode is

Binary

but in rare cases the

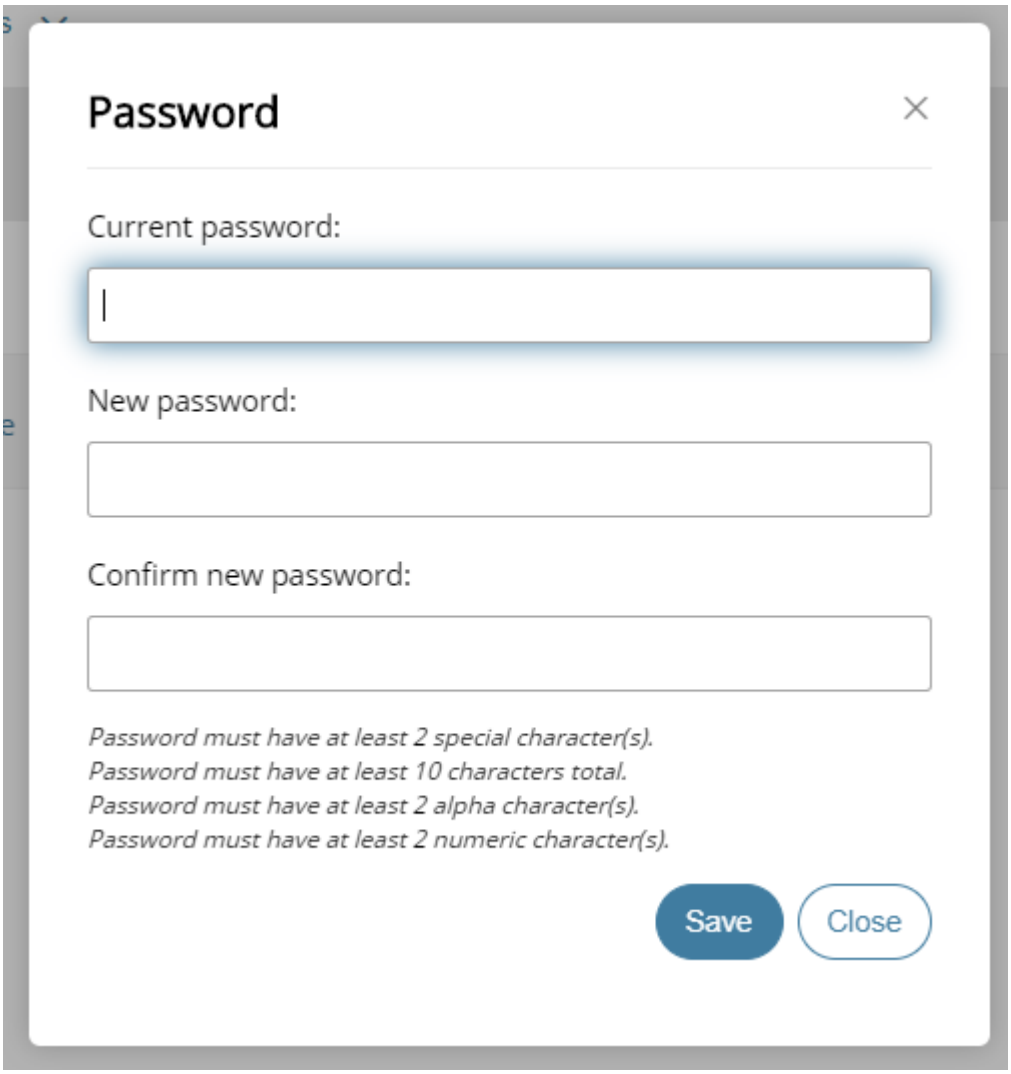
ASCII

mode may be required for XML, HTML, or TXT files.

Click **Save**.

Select the **Welcome** drop-down.

Click **Password**. The Password pane opens.



1. Enter your Current password.
2. Enter your new password.
3. Confirm new password.
4. Click **Save**.

Upload files

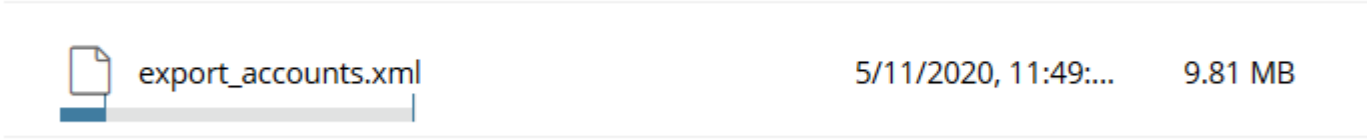
To upload files to ST Web Client you click the **Upload** button.

From your files pane, click **Upload**.

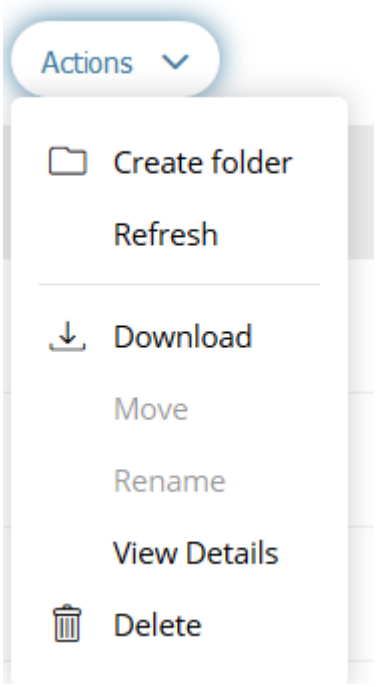
Select the file or files to upload. Use the **Ctrl** or **Shift** keys to select multiple files.

Click **Open**.

The below will be display showing progress of your file upload.



Actions Drop Down Menu



Download files

To download files from ST Web Client you click to the left of this icon  on your files pane. Use the **Ctrl** or **Shift** keys to select multiple files.

Click Action dropdown and select Download.

A popup will ask you to “Open” or “Save File”. Note: Ensure data accuracy and completeness of data download utilize the “Save File” choice.

Create folders

To create folders

Select **Create folder** from the Actions Drop Down.

The Create folder pane opens.

Enter the folder name.

Click **Create**. The new folder is created and displayed on the "Your Files" pane and a message is displayed.

Delete files and folders

To delete a file or folder:

From the "Your Files" pane, select the file or folder to delete. Use the **Ctrl** key to select multiple files.

Select **Delete** from the Actions Drop Down menu. The delete confirmation pane opens.

Click **Delete** to confirm.

View file or folder details

You can view the following details of files and folders:

For files, the View Details pane lists Modified, Size, and Owner details.

For folders, the View Details pane lists Modified and Owner details.

To view file or folder details

From the "Your Files" pane, select a file or folder.

Select **View Details** from the Actions menu.

The View Details pane is displayed.

Click **OK**

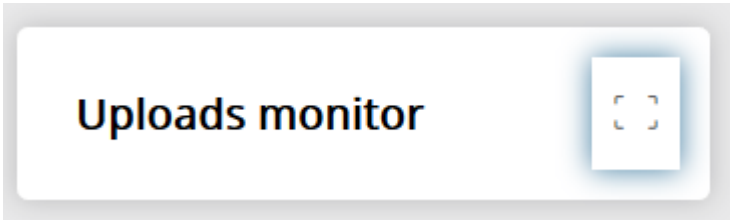
Delete files and folders

To delete a file or folder:

From the "Your Files" pane, select the file or folder to delete. Use the **Ctrl** key to select multiple files.

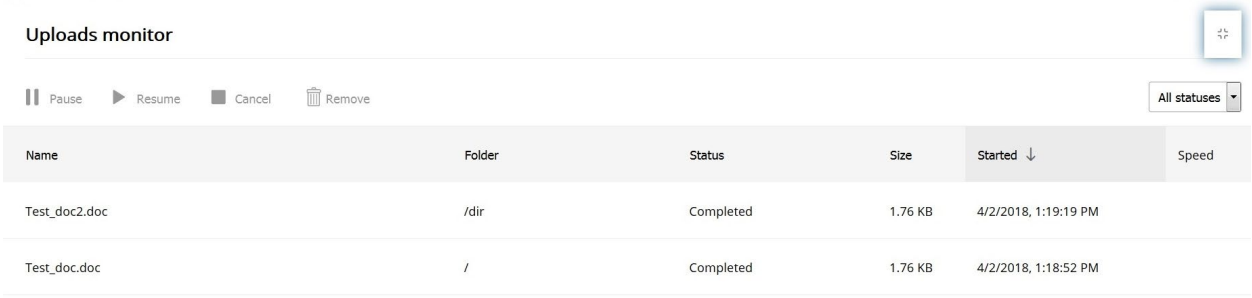
Select **Delete** from the Actions menu. The Delete confirmation pane opens.

Click **Delete** to confirm



Monitor uploads

At the bottom of the "Your Files" pane, click **Uploads monitor**. The Uploads monitor pane is displayed:



Information Displayed

The current status of the file uploads

The progress of each upload if in upload processing

Name of file uploaded/uploading

Folder placement of File

Size of File

Start time & date of Upload

Filter uploads displayed

To filter uploads displayed on the Uploads pane, select the desired filter on the Status drop-down menu.

All statuses

Running

Completed

Paused

Canceled

Failed

Pause uploads

To pause an upload:

Select uploads you want to pause. Use the **Ctrl** key to select multiple uploads.

Click **Pause**.

Resume uploads

To resume an upload:

Select uploads that are paused that you want to resume. Use the **Ctrl** key to select multiple uploads.

Click **Resume**.

Cancel uploads

To cancel an upload:

Select the upload that is running that you want to cancel. Use the **Ctrl** key to select multiple uploads.

Click **Cancel**.

Remove display entries

To cancel an upload:

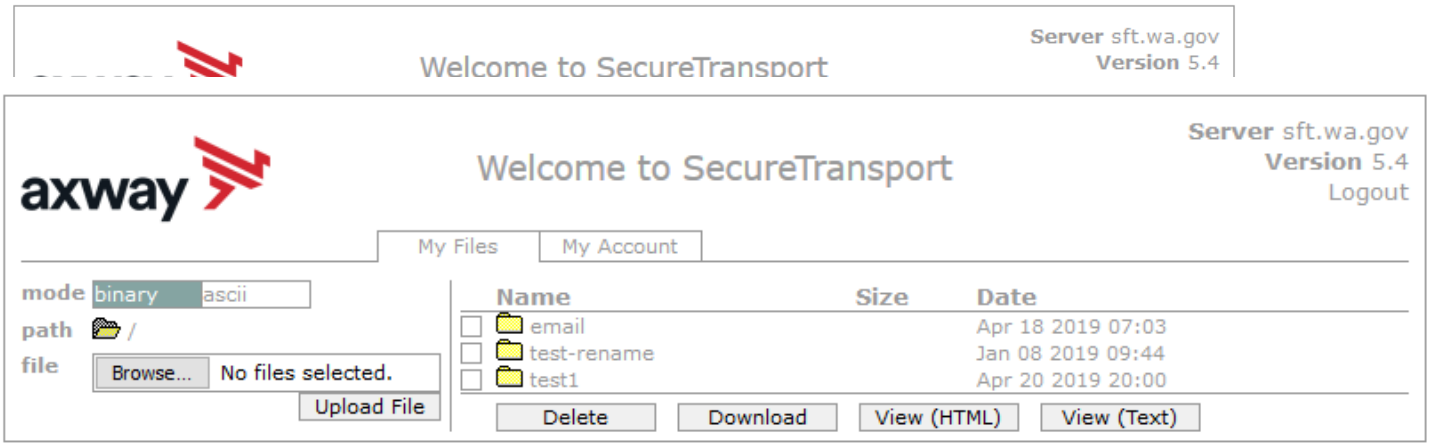
Select the upload that is running that you want to cancel. Use the **Ctrl** key to select multiple uploads.

Click **Remove**.

SFT Client Options – Partial List of

WaTech supported clients-

Default browser client



Here is the screen after successful login-

Upload a file by selecting "Browse" tab

Select a file and hit the "Open" tab

The file will appear to the right of the Browse tab.

Select the "Upload File" tab

The file name will be displayed.

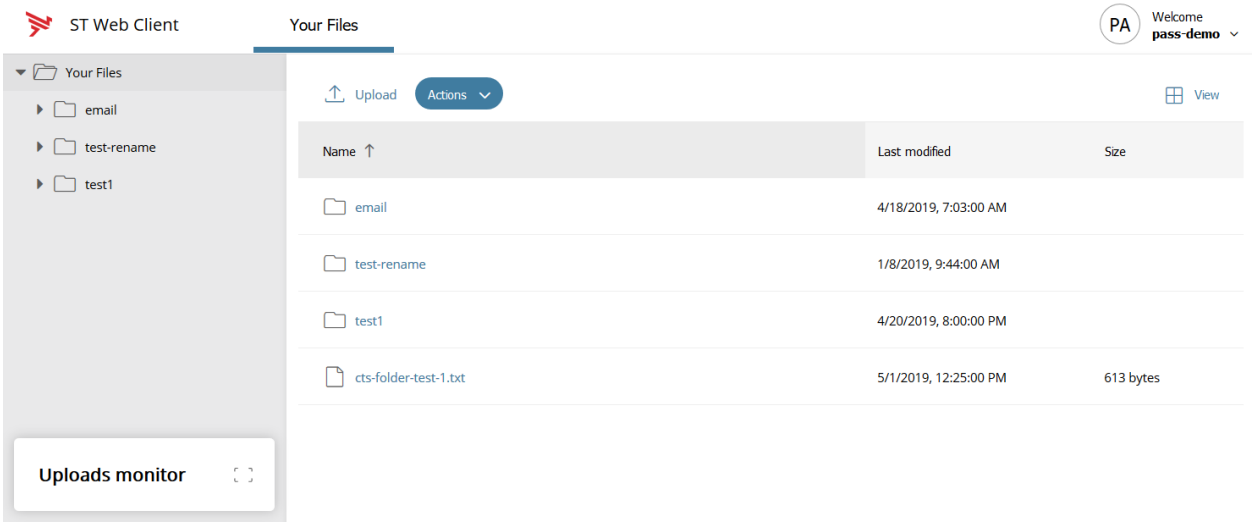
Download a file

Check the box to left of your file to download.

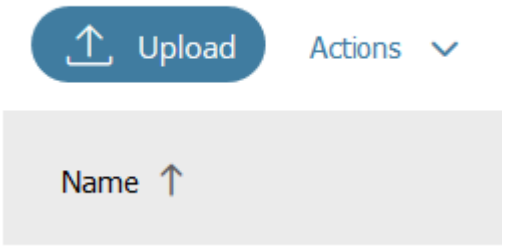
Select the "Download" tab

Please do not download a file by selecting the "View" tabs. As you may not get a complete file downloaded.

After entering your credentials in the default client above, if your account is assigned the ST Web Client, this screen will appear:



Upload a file by selecting "Upload" tab



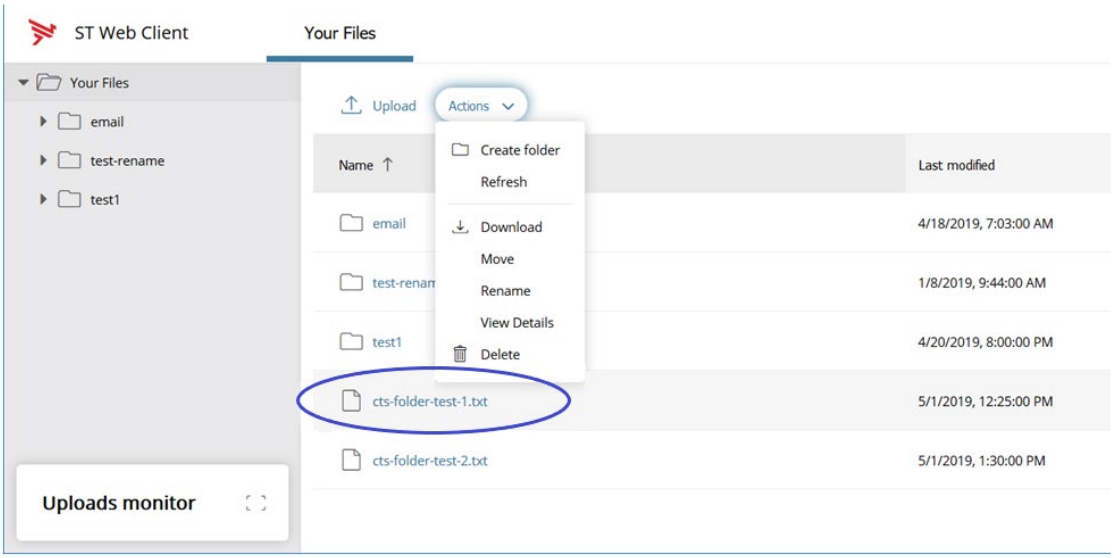
Your local folders will be displayed (It defaults to your last location)

Select a file and hit the "Open" tab and this completes the operation of upload. You will get some information on the screen in regards to the file transfer.

Download a file by

On the screen highlight the file you want to download.

Click on “Actions” drop down will appear, select “Download”

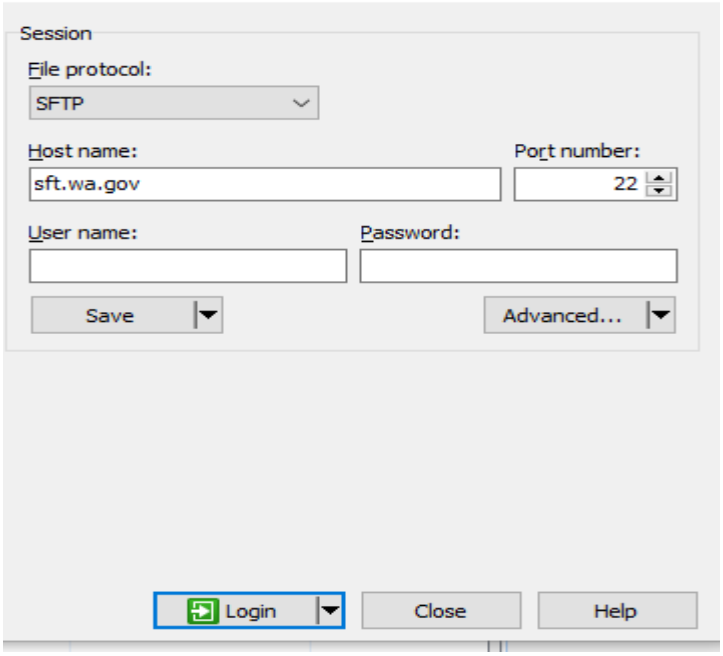


Optional Clients

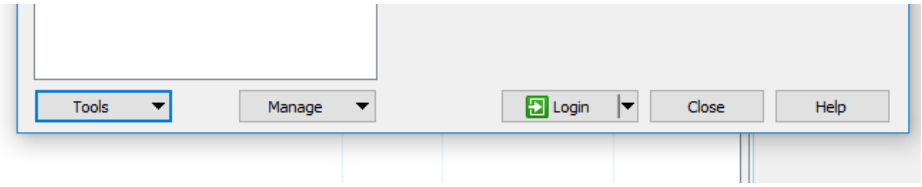
WaTech **does not support** any third party client or provide technical support.

WinSCP – With Basic setup information and requirements

URL and Port requirements-



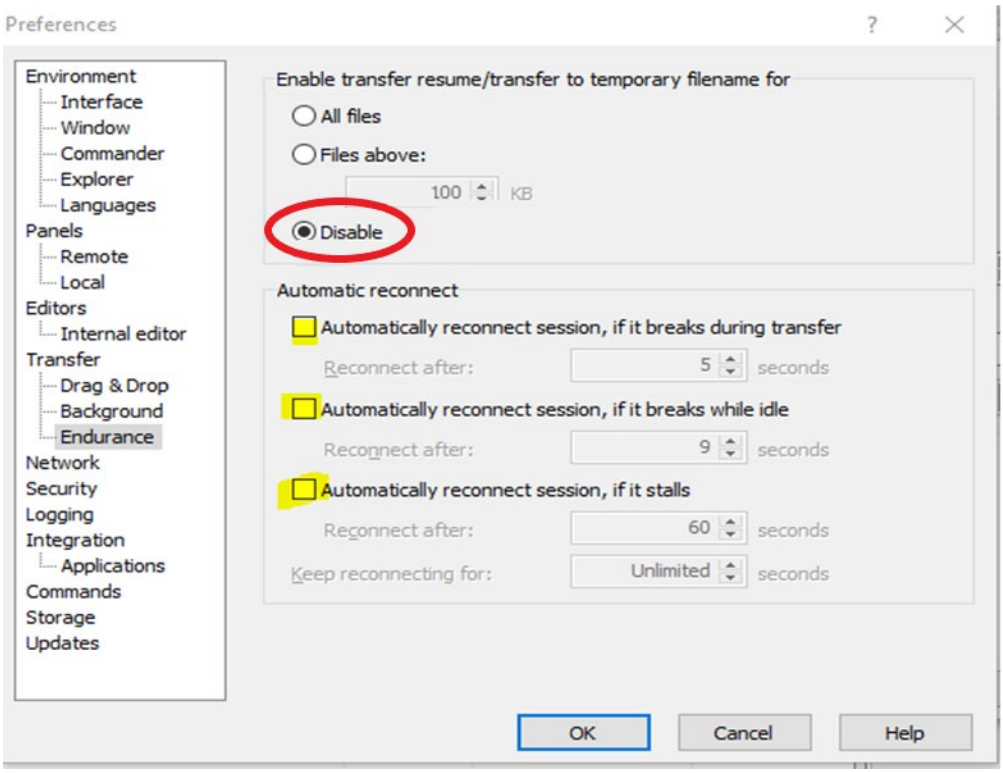
Setting requirement to work with SFT. Need to Disable



On the right hand corner of the Login pop up, select the "Tools" tab

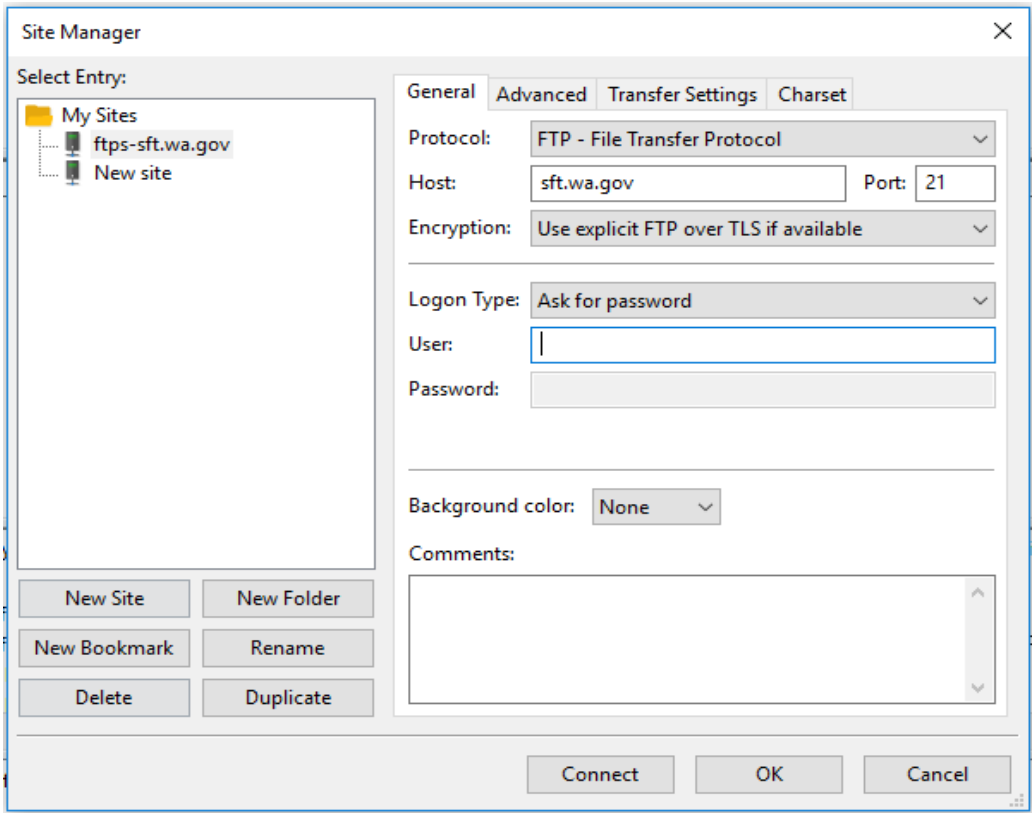
Click on "Endurance" tab and disable the resume feature circled in red.

The yellow highlight is your choice of operation.

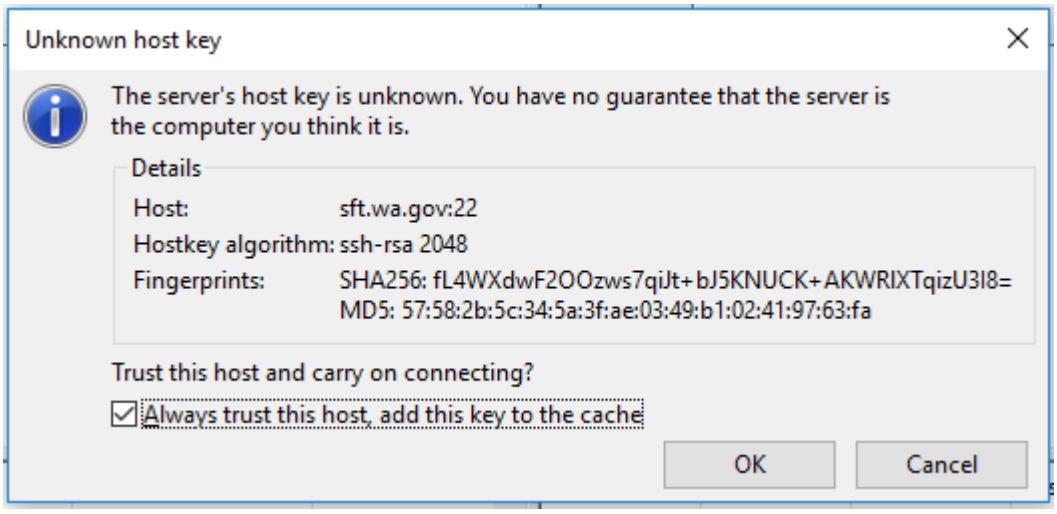


FileZilla- Basic information

Using FTPS-



If using ssh/sftp port 22 need to accept the key on initial login.



Other client information-

General-

SFT is expected to work properly with any client or server software which complies with:

RFC 959, RFC 2228, RFC 2389, RFC 2428, RFC 2640, RFC 4217, MD5 Command Extensions, MFxx Command Extensions for FTP transfers

RFC 4251, RFC 4252, RFC 4253, RFC 4254, Draft RFC - Secure Shell File Transfer Protocol, Draft RFC - SSH File Transfer Protocol draft-ietf-secsh-filexfer-04.txt for SFTP and SCP transfers.

List of certified client software by the vendor for file exchange

Software	Versions	Protocols
cURL	7.58.0	FTPS, HTTPS
CuteFTP Professional	9.2.0.8 (Windows)	FTPS
LFTP	4.8.3	FTPS
PSCP (PuTTY)	0.70	SSH
PSFTP (PuTTY SFTP)	0.70	SSH
SmartFTP Client	9.0.2558.0	FTPS
Tectia SSH Client	6.4.15	SSH
VanDyke SecureFX	8.3	SSH
WGET	1.13	FTPS, HTTPS