TENNESSEE CONTROLLED SUBSTANCE DATABASE

DATA COLLECTION MANUAL

Effective: December 12th 2011

Optimum Technology, Inc.

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TENNESSEE CONTROLLED SUBSTANCE DATABASE

In accordance with Tennessee Annotated Code §53-10-301*, et seq*., the Tennessee Department of Health has established a program to monitor the prescribing and dispensing of Schedules II, III, IV & V controlled substances. The program began for all dispensers on December 1, 2006. The program requires a dispenser, licensed in the State of Tennessee, that dispenses controlled substances in schedules II, III, IV and V, within or from outside of the State of Tennessee, to patients in the State of Tennessee to submit the required information. The program covers the entire state and requires all dispensers to report at least twice a month. Both resident and non-resident pharmacies and other dispensers are required to report.

REPORTING THE DATA

Dispensers will report the required dispensing information to Optimum Technology, Inc. (Optimum), a private contractor, which will collect all data and manage the technical aspects of the program.

Toll-free number for Optimum: 866-683-9771
Email for technical assistance: **tnrxreport@otech.com**

Such reporting without individual authorization by the patient is allowed under HIPAA, 45CFR § 164.512, paragraphs (a) and (d). The Tennessee Board of Pharmacy is a health regulatory agency and Optimum is acting as an agent of Tennessee Board of Pharmacy in the collection of this information.

Attention:

The upgraded website will be available on December 12, 2011.
ASAP 95 files will continue to be accepted by the program until March 31, 2012.
Effective April 1, 2012 files must be in ASAP 2009 v4.1 format. Files not in this format will be rejected by the system.

All transactions must be submitted at least twice monthly. The deadline for reporting dispensing between the 1st and 15th of each month is the 25th of that month. The deadline for reporting dispensing between the 16th and the last day of the month is the 10th of the next month. Dispensers are encouraged to report prior to the deadline in order to have time to correct any rejected submissions. Dispensers who so choose may report more frequently than twice a month, for example, weekly or daily.

REPORTING PROCEDURES and FILE TYPES

Only **Schedule II-V** prescription dispensing information is to be reported. All dispensers licensed by the State of Tennessee that dispense Schedules II-V controlled substances are required to submit the information by one of the following data submission options.

1. Website Upload/Prescription File Uploads

The user must use the login credentials provided to sign into the user account at the following website: **www.tnrxreport.com**. You may also register for account access at this website.

This secure website address is provided for uploading data to Optimum, which utilizes 256-bit encryption. Dispensers are able to access the secure website via a web browser.

Please inform your software vendor that you will need to be able to upload your data in the ASAP 2009 v4.1 format as a .DAT or .TXT file. (*ASAP 95 is accepted until March 31, 2012*)

Your file will need to be named according to the following rules: your DEA number, the date submitted, followed by **.DAT** or **.TXT**

Therefore, if your DEA number is *AB1234567* and you are submitting on August 1, 2006, the file would look like this: ***AB1234567****080106****.dat*****.**

Please name your files accordingly when submitting your controlled substance information. This will assist you with keeping accurate records of the information reported to Optimum and will assist with locating this information in a timely and efficient manner, should this be necessary.

Uploading your file:

1. Go to the **Data Collection menu** > Choose **File Upload**
2. **Click Browse** to locate your file,
3. Highlight the File, then **Click Open** (the file will populate in the File Name field)
4. **Click Upload** to send the file to Optimum
5. You will receive confirmation via the web page that your file was successfully submitted and will be processed by the batch processor within 24hrs.

You may View all uploaded files, and their status, on the "View Uploaded files" tab on the File Upload page. This page will show a history of all files submitted to the program, their status, and any errors contained within the file. Corrections may also be made via the View Uploaded Files tab. (*See the section "Errors and Corrections".)*

2. CD-Rom, CD-R, CD-RW, DVD or 3 1/2" Diskette (A transmittal form must accompany all submissions.)

A Program Transmittal Form (Attachment 1) should accompany external media submissions. The dispenser should make copies of the enclosed, blank Program Transmittal Form for future use or print a blank form from **www.tnrxreport.com** . The dispenser may also wish to keep a copy of the completed form for its records.

This file must also contain an external media label, with the following information:
Pharmacy/Submitter Name, DEA number, and the number of prescriptions.

These media forms must be mailed to:
Optimum Technology, Inc.
Attn: Data Collection
100 E Campus View Blvd
Suite 380
Columbus, OH 43235

3. FTPs Transfer - Pharmacy – FTPs account

Chain Pharmacies and Community Pharmacies with multiple facilities may submit one data transmission on behalf of all of their facilities. In fact, the program prefers that chain pharmacies and community pharmacies with multiple facilities submit one transmission with the data for all of their facilities. They may do so utilizing the FTP procedure. *If they wish to do so, during registration they must appoint one contact person for all of their data submissions.*

Chain pharmacies should seek direction from their corporate offices concerning how their data will be reported. Corporate offices and their software vendors should register at **www.tnrxreport.com**, as a Pharmacy- FTP user, to obtain a user id and password. The host name for transfer is **www.tnrxreport.com.** Optimum only supports FTPs transmission. Login credentials will be emailed to the email address listed in the registration within 24-48 business hours.

(Zero Reports via FTPs can ONLY be submitted in the ASAP 2009/v4.1. Please see the section titled 'zero reports' for additional information.)

4. Zero Reports

If a pharmacy does not dispense any Schedule II-V prescriptions during a reporting period, a "zero" report should be submitted. This may be done via the prescription upload website: **www.tnrxreport.com** under the Data Collection menu.

To Access the Zero Reporting screen in the data collection portal:

1. Login to **www.tnrxreport.com** with your username and password.
2. Go to the **Data Collection menu**.
3. Click on the option **Upload Pharmacy Zero Report**.
4. Select the reporting period for zero report submission.
5. Click **Submit**.

Chain pharmacies should seek direction from their corporate offices concerning how their data (zero reports) will be submitted. *Zero reports can only be submitted via a web account specific to the dispensers DEA # or via FTPs in ASAP 2009/v4.1.*

Zero reports via FTPs transmission in ASAP 4.1 format:

The Zero Report standard is a complete transaction and includes all fields required by the CSMD program according to the states requirements. Transaction Headers and Trailer Segments are completed as they would be with a normal controlled substance report. All required detail segments are to be sent and left blank with the exception of the PAT07; PAT08; and DSP05. The segments should be completed accordingly: PAT07 = Report; PAT08 = Zero; DSP05 = Date report is sent.

Alternative Reporting Methods

If the dispenser does not have an automated recordkeeping system or can show that electronic reporting by any of the above means creates an undue hardship, a waiver may be granted by the Committee that would allow the dispenser to submit in one of the following alternative formats. The application for the waiver must be completed and submitted to the CSMD Administrator and acted upon by the Committee before it is effective. (Form attached)

Manual Entry

1. A dispenser, after being granted a waiver by the Committee, may submit prescription information on the Manual Entry page via a link on the prescription upload website: **www.tnrxreport.com**

A sample of the information required to fill out this form is attached (Attachment 2).

To Access the UCF Manual Entry screen in the data collection portal:

1. Login to **www.tnrxreport.com** with your username and password.
2. Single click left mouse button on **Data Collection Menu**.
3. Single click left mouse button on **Manual Entry**.
4. As explained in the '**WHAT DATA IS MANDATORY, WHAT IS OPTIONAL**' section, the dispenser must have at least the mandatory data available to enter manual prescriptions.

2. The second alternative form utilizes the Universal Claim Form (attached) which will be mailed to Optimum Technology after the dispenser has been granted a waiver by the Committee.

ERRORS and CORRECTIONS

Rejections

The CSMD application will validate each file submitted, record by record, and will reject those records which do not meet the validation requirements. If there are a limited number of errors, only those records with errors will be rejected. The user will be notified via email & the message center of the status of the file, and the errors contained within.

If the records in a file do not meet the required data specifications, the entire file may be rejected. **In this instance, the submitter will be notified via email and/or the 'Message Center' of the reason for this failure.** (A valid email address is required for email notification.)

Optimum is not authorized to modify any data; therefore, the dispenser will be required to correct these errors through the website or resubmit the entire file, if necessary.

Viewing your Errors and File Upload Status:

The Data Collection Portal allows all users to login and view the status of their Uploaded Files. A history of all files submitted to the program can be viewed on the View Uploaded Files tab under the Data

Collection Menu. This page will also show the user any errors associated with a particular file, and will allow the user to make corrections to these errors through the website. Please follow the details below to view your uploaded files and any errors associated with those files.

View File Upload Errors:

1. Login to **www.tnrxreport.com** with your username and password.
2. Go to the **Data Collection Menu** > Click on **File Upload.**
3. Click on the **View Uploaded Files tab**. This will display a history of all files submitted.
4. Click on the File containing errors that you wish to correct.
5. Click on each individual error to see a detailed description at the bottom of the page.

Prescription Corrections:

There are two options to correct the data as detailed below.

1. **Correct the data in your retail RX software; regenerate the file and upload the data.**

    a. Please note this process may result in duplicate records as a portion of the records originally submitted were accepted. **The duplicate records require no action on the part of the pharmacy or dispenser**.
    b. *You may also choose to correct only those records that were rejected and create a separate file to submit. This will eliminate any chance of your file being rejected for duplicate records.*

2. **Correct the data online via the Data Collection Portal. This type of correction is manually performed and makes sense when there are minimal errors.**

    a. Login to **www.tnrxreport.com** with your username and password.
    b. Go to the **Data Collection Menu** > Click on **File Upload.**
    c. Click on the **View Uploaded Files tab**. This will display a history of all files submitted.
    d. Click on the File containing errors that you wish to correct.
    e. To the right of each error, click on the **paper/pencil icon**  . You will then be shown a Prescription correction screen.
    f. Correct the fields indicated, click the authorization checkbox, and then Click Save.
    g. You will receive an online confirmation that your file was successfully saved.

Prescription Maintenance:

For security purposes, data cannot be deleted by Optimum once it is submitted to the program. To remedy this situation, go to the Prescription maintenance page under the Data Management menu. Search for the RX by prescription number, Dispenser DEA, Prescriber DEA, Date filled or any combination of these criteria. You can then update the information by changing the Reporting Status to, 'revise' to update the RX, or 'void' to delete the RX. Click the confirmation box and hit 'Save'.

Test Run Upload Feature:

This feature is provided to assist the user with identifying errors within a file, prior to submitting the information to Optimum for reporting purposes. It is located in the Upload Center within the Data Collection website. The feature can be used for any type of file that it is submitted directly through the **www.tnrxreport.com** website.

The process is similar to submitting your completed file, but will allow the user to see any errors, and correct those errors prior to your submission to the State reporting agency.

If you have attempted to submit your file, and are receiving rejection notices or extensive errors, please utilize this function. This function may also assist your software vendor with helping to identify any corrections that may be needed related to software or the format of your file.

EXEMPTIONS FROM REPORTING:

Exemptions:

- Dispensing of manufacturer's samples
- Any drug dispensed by a licensed health care facility; provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.
- A drug administered directly to a patient
- Dispensing within an appropriately licensed narcotic maintenance treatment program by the United States Drug Enforcement Administration.

If you wish to submit a request for exemption from reporting please fill out the attached exemption/waiver request form and mail to:

Department of Health Related Boards
Tennessee Board of Pharmacy
Controlled Substance Database
227 French Landing Drive, Suite 300
Nashville, TN 37243
Or submit by FAX to (615) 253-8782

The exemption request must be approved by the Committee before it is effective.

WHAT DATA IS MANDATORY, WHAT IS OPTIONAL?

Controlled Substance Schedule II - Summary of ASAP 2009 v4.1 Data Elements

Note: ASAP Version 4 • Release 1 is used

Visit www.asapnet.com to purchase a complete implementation guides for all ASAP standards in the online bookstore.

Ref. Code	Data Element Name	Format	Attributes*
HEADER SEGMENTS			
			Required Data
TH TRANSACTION HEADER – (TH01-TH09)			
TH01	Version/Release Number	4.1	Yes
TH02	Transaction Control Number	See TT01; GUID is recommended	Yes
TH05	Created Date	CCYYMMDD	Yes
TH06	Creation Time	HHMMSS or HHMM	Yes
TH07	File Type	P = Production; T = Test	Yes
TH09	Segment Terminator Character	Examples: ~~ or || or ::	Yes
IS INFORMATION SOURCE – (IS01-IS03)			
IS01	Unique Information Source	(Ex: Phone number)	Yes
IS02	Information Source Entity Name	Pharmacy Name	Yes
PHA DISPENSING PHARMACY – (PHA01-PHA12)			
PHA03	DEA Number		Yes
DETAIL SEGMENTS			
PAT - PATIENT DETAIL SEGMENT – (PAT01-PAT23)			
PAT07	Last Name		Yes
PAT08	First Name		Yes
PAT12	Address Information – 1		Yes
PAT14	City Address		Yes
PAT15	State Address		Yes
PAT16	ZIP Code Address	"00000" Non-US	Yes
PAT18	Date of Birth	CCYYMMDD	Yes
PAT19	Gender Code	F-Female, M-Male, U-Unknown	Yes
DSP - DISPENSING DETAIL SEGMENT - REQUIRED			
DSP01	Reporting Status	"00" New record; "01" Revise; "02" Void	Yes
DSP02	Prescription Number		Yes
DSP03	Date Written	CCYYMMDD	Yes
DSP04	Refills Authorized		Yes
DSP05	Date Filled	CCYYMMDD	Yes
DSP06	Refill Number	0 = indicates original dispensing; 01-99 is the refill number	Yes
DSP07	Product ID Qualifier	"01" NDC# or "06" compound	Yes
DSP08	Product ID	NDC# or "99999999999" for compound; If a compound the CDI segment is required	Yes
DSP09	Quantity Dispensed	Metric decimal format	Yes
DSP10	Days Supply		Yes
DSP11	Drug Dosage Units Code	"01" = Each (solid dosage units or	Yes

Ref. Code	Data Element Name	Format	Attributes*
		indivisible packages) "02" = ml "03" = gm (values must be converted to liter/ mg equivalent)	
DSP16	Classification Code for Payment Type	01 = Private Pay (Cash/Charge) 02 = Medicaid 03 = Medicare 04 = Commercial Insurance 05 = Military and VA 06 = Workers Compensation 07 = Indian Nations 99 = Other	Yes
PRE - PRESCRIBER DETAIL SEGMENT - REQUIRED			
PRE02	DEA Number		Yes
CDI - COMPOUND DRUG INGREDIENT DETAIL SEGMENT - If DSP07 = 06 all CDI segments required			
CDI01	Compound Drug Ingredient Number	1st reportable ingredient is "1"; additional ingredients are incremented by 1.	SIT
CDI02	Product ID Qualifier	"01" = NDC#	SIT
CDI03	Product ID	As indicated in CDI02	SIT
CDI04	Compound Ingredient Quantity	Metric Decimal quantity	SIT
CDI05	Compound Drug Dosage Units Code	"01" # of units or "02" ml or "03" gm	SIT
AIR ADDITIONAL INFORMATION REPORTING - SITUATIONAL			
All Segments optional.			
SUMMARY SEGMENTS			
TP - PHARMACY TRAILER – REQUIRED			
TP01	Detail Segment Count	Includes PHA; all Detail segments & TP segment	Yes
TT01	Transaction Control Number	Must match TH02	Yes
TT02	Segment Count	Total # of segments, including header and trailer segments	Yes

*** AN-Alphanumeric, N-Numeric, D-Decimal, DT-Date, TM-Time (24hr clock)**

This page constitutes a summary of the required ASAP information for controlled substance reporting in TN. Additional information must be obtained by purchasing an implementation guide at www.asapnet.org.

FREQUENTLY ASKED QUESTIONS:

Passwords and sign-in information:

Does my password expire?
For security purposes, passwords will expire every 180 days. You do not need to remember to update your password, as the system will automatically prompt you to change your password after 180 days.

Please note that your account will require you to update your password upon your initial sign-in. At this time, please answer the security questions provided. This will allow you to change/update your password during the evening/weekend hours.

I have entered my password numerous times, I am sure that it is correct? Why is this happening?
Please consider the type of information that you are attempting to locate. If you are attempting to submit records of your dispensed controlled substances, please go to the link 'Forgot my password'. If you have answered the security questions provided, you will be able to reset your password using this function.

If you are attempting to view patient information, or prescription history, please verify that you are accessing the correct website.

Prescription Data and Reporting requirements:

What is the NDC Code?
The National Drug Code is an 11 digit number used to identify drug strength, name, quantity etc. This number is found on the medication bottle.

What drugs should be reported?
The Controlled Substance Monitoring Database collects drug schedules II-IV.

How often should I submit data?
All transactions must be submitted at least twice monthly. The deadline for reporting dispensing between the 1st and 15th of each month is the 25th of that month. The deadline for reporting dispensing between the 16th and the last day of the month is the 10th of the next month. Dispensers are encouraged to report prior to the deadline in order to have time to correct any rejected submissions. Dispensers who so choose may report more frequently than twice a month, for example, weekly or daily.

How are compounded prescriptions to be recorded?
Prescriptions compounded by the pharmacist and containing a controlled substance must be reported. To submit a compound controlled substance, the field DSP07 must indicate this by the value '06' for compound. Subsequently, DSP08 must then be reported as eleven "9's" or 99999999999. By reporting the value in DSP07 as '06', the CDI segment then becomes a mandatory or required segment.

The CDI segment will require that reportable controlled substances be reported in increments of 1 in field CDI01; the NDC code is reported as '01' in CDI02; and the NDC of those reportable ingredients is provided in CDI03. The quantity is provided in metric decimal format in CDI04; and the Drug Dosage Units Code is reported in CDI05.

Why is the system rejecting the input metric quantity?
The metric quantity should be the number of metric units dispensed in metric decimal format. (Ex: 3.5)

What should I do if the pharmacy / doctor I am reporting meets one of the conditions to be considered exempt from reporting?
If exempt from reporting, please fill out the request for waiver or exemption (attachment 3) and follow the instructions listed. This request must be approved by the Committee before it becomes effective.

I received a Delinquency Letter; what should I do?
If you received a Delinquency letter and would like to check the status of your data, please send an email to **tnrxreport@otech.com** with the following information (If you are unsure if your data was submitted, resubmit the time period in question. This request will take one day to process. Please provide:
1. Username
2. Reporting period(s) in question

If a confirmation is required, you may forward Optimum Tech's email response to the CSMD Administrator as confirmation your data was received.

File issues and Error Corrections:

What should the filename be?
The filename should be the DEA number, followed by the date of submission, followed by **.dat or .txt.** Chain pharmacies may use the chain name, followed by the date of submission. The filename is less important than the contents of the file.

FTP users should be certain to differentiate files by adding to the filename before the **.dat or .txt** extension. This will ensure that the contents of the file are not overwritten. FTPs submissions with the same filename, submitted on the same day will overwrite the previously submitted file.

What does the file status 'Pending' mean?
Uploaded files will be processed overnight by a batch processor, therefore they will be in 'Pending' status until the day following upload. You will receive notification via the message center and email, if you have supplied a valid email address. You can update this information in the My Accounts section of the website.

I do not work with a software vendor; how should I submit controlled substance data?
If you do not work with a software vendor, you will need to manually enter controlled substance data. To submit manually, go to Data Collection > Manual Entry. Complete all required fields and click save; no further action is required.

I accidentally sent the incorrect reporting period. Should the file be deleted?
If the wrong reporting period was uploaded, the file does not need to be deleted. Records that have already been processed by the system will be rejected as duplicate records. To remedy this issue, simply create a file with the correct reporting period and upload again.

What should I do if my file was rejected?
If your file was rejected, do a Test Run Upload. To do this, go to the Data Collection Menu > Test Run Upload and submit your file. The bottom of the screen will list file format problems. Missing or invalid fields should be corrected by your software vendor.

How do I know if my file uploaded?
1. Go to Data Collection > File Upload
2. Click on the View uploaded files tab
3. You will be able to view all files submitted

If you are not receiving email notifications, you will need to verify that your email address is listed *correctly*. Go to 'My Account' and enter your email address in the appropriate field, you will also receive file status notifications in the section of your account titled 'messages'.

An email will be sent (the following day) confirming the file's processing status and any errors contained within that file.

(Please be sure to add the domain: otech.com to your safe sender's list within your email client. This will ensure that you receive communications from Optimum in a timely manner.)

I accidentally submitted incorrect information. Can I delete a record/entry?
The ASAP 2009 v4.1 formatting requirements allow for the following functions: 'new, revise or delete'. For those sending electronic files, please refer to DSP01 in the formatting table.

For users that submit manual entries, you are able to update previously submitted information. Please refer to the "Prescription Details" section on the manual entry page.

Why are there no menus displayed on the web page?

If you are using Internet Explorer version 6.0 or higher, check which version you are currently using. Go to Help > About Internet Explorer. Verify that Compatibility mode is enabled. This can be found in the 'Tools' menu or your internet browser.

How do I fix "duplicate" error messages?
A duplicate error message displays when a data record is received and processed more than once. This normally occurs when a file is uploaded after correcting errors in your prescription software or when a file is uploaded twice in error for a different reporting period. *The duplicate records occurring as a result of duplicate file uploads require no action on the part of the pharmacy or dispenser.*

OTHER QUESTIONS:

How do I setup an FTP account?
FTP account requests must be made via the registration page on **www.tnrxreport.com**. You will need to register for the job type 'Pharmacy – FTPs'. You will receive login credentials at the email address indicated in your registration within 24-48 business hours.

How should the address for a patient not from the U.S. be entered to be accepted by the program?
Non-US zip codes or residents should have the value '00000' placed into the zip code category.

ASSISTANCE AND SUPPORT

Optimum is available to provide assistance and information to individual pharmacies, chain pharmacies, software vendors, and other entities required to submit data. Technical support is available to meet the program requirements. Questions concerning interpretation of technical and compliance matters may be referred to Optimum. Dispensers are advised to first contact their software vendor to obtain modifications and instructions on compliance and participation. Software vendors may also contact Optimum directly for assistance.

The Controlled Substance Advisory Committee will act as the final interpreter of regulations.
Unresolved disagreements between a dispenser and Optimum Tech will be resolved by the Committee.

Controlled Substance Database Contact Information:
For questions: call the Tennessee Board of Pharmacy (615) 253-1305 or e-mail CSMD.admin@tn.gov.

Attachment 1
Program Transmittal Form

File Name: _____ Date: _____
The file name should be the DEA number followed by .DAT (example: AB01123456.DAT)

Pharmacy/Dispenser Name: _____

DEA Number: _____

Number of Prescriptions in File: _____

Name of person submitting report: _____

Phone Number: _____ Fax Number: _____

External/diskette label must contain: Pharmacy/Submitter Name, DEA Number and Number of Prescriptions

Attachment 2

DEPARTMENT OF HEALTH RELATED BOARDS
TENNESSEE BOARD OF PHARMACY
Controlled Substance Database
227 French Landing Drive, Suite 300
NASHVILLE, TENNESSEE 37243-1149
(615) 253-1305 OR FAX (615) 253-8782

UNIVERSAL CLAIM FORM

DEA # ______________________

Last Name	First Name	DOB	Gender	Address	City	State	Zip
ID Type *	ID # *	Issuing State*	Prescriber DEA #	New/Change/Purge	RX #	DT written	Auth Refills
Date Filled	Days Supply	Refill #	Qty	Product ID (NDC/UPC/CMPD #)	Gm/ml	Payment Type	

Last Name	First Name	DOB	Gender	Address	City	State	Zip
ID Type *	ID # *	Issuing State*	Prescriber DEA #	New/Change/Purge	RX #	DT written	Auth Refills
Date Filled	Days Supply	Refill #	Qty	Product ID (NDC/UPC/CMPD #)	Gm/ml	Payment Type	

Last Name	First Name	DOB	Gender	Address	City	State	Zip
ID Type *	ID # *	Issuing State*	Prescriber DEA #	New/Change/Purge	RX #	DT written	Auth Refills
Date Filled	Days Supply	Refill #	Qty	Product ID (NDC/UPC/CMPD #)	Gm/ml	Payment Type	

NOTE : The above form serves as an example only. Do not submit this form for reporting purposes.

Attachment 3

TENNESSEE DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
Controlled Substance Database Administrator
227 FRENCH LANDING, SUITE 300
NASHVILLE, TENNESSEE 37243
(615) 253-1305 OR FAX (615) 253-8782

DISPENSER EXEMPTION OR WAIVER REQUEST

Please provide the information requested below. (Print or Type)

Name of Dispenser/Pharmacy:	Dispenser Regulatory Board License Number:
DEA Registration Number:	
Street Address:	City:
State: Zip:	Telephone Number: ( )
Name of Pharmacist in Charge:	Pharmacist in Charge TN License Number:
Signature:	Date:

"Dispense" means to physically deliver a controlled substance to any person, institution, or entity with the intent that it be consumed away from the premises in which it is dispensed. It does not include the act of writing a prescription by a practitioner to be filled at a pharmacy licensed by the board.

Request for exemption from reporting:

☐ This dispenser does not hold a controlled substance registration with the Drug Enforcement Administration (DEA).

☐ This dispenser holds a DEA Registration but does not dispense any controlled substances.

☐ This dispenser is exempt from reporting according to T.C.A. 53-10-304(d) (Not required to report by alternate means)

- ☐ Drug is administered directly to an inpatient
- ☐ Drug is dispensed by a licensed healthcare facility dispensing an amount to treat for 48 hours maximum
- ☐ Dispensing drug samples
- ☐ Dispensing in a narcotic treatment program

Request for waiver of electronic reporting:

☐ This dispenser is entitled to a waiver from electronic reporting according to Rule 1140-11-04(4) or T.C.A 53-10-305(d)(1).

- ☐ This dispenser does not have an automated recordkeeping system capable of producing an electronic report of the required data in the format established by the "ASAP Telecommunications Format for Controlled Substances". (Must report by alternate means)
- ☐ Electronic reporting would cause undue hardship (attach explanation). (Must report by alternate means)

For Department Use Only

Date Received	☐ **Approved** ☐ **Disapproved**	**Director or Designee Signature**	**Date of Notification**