



MDS SOMS Software

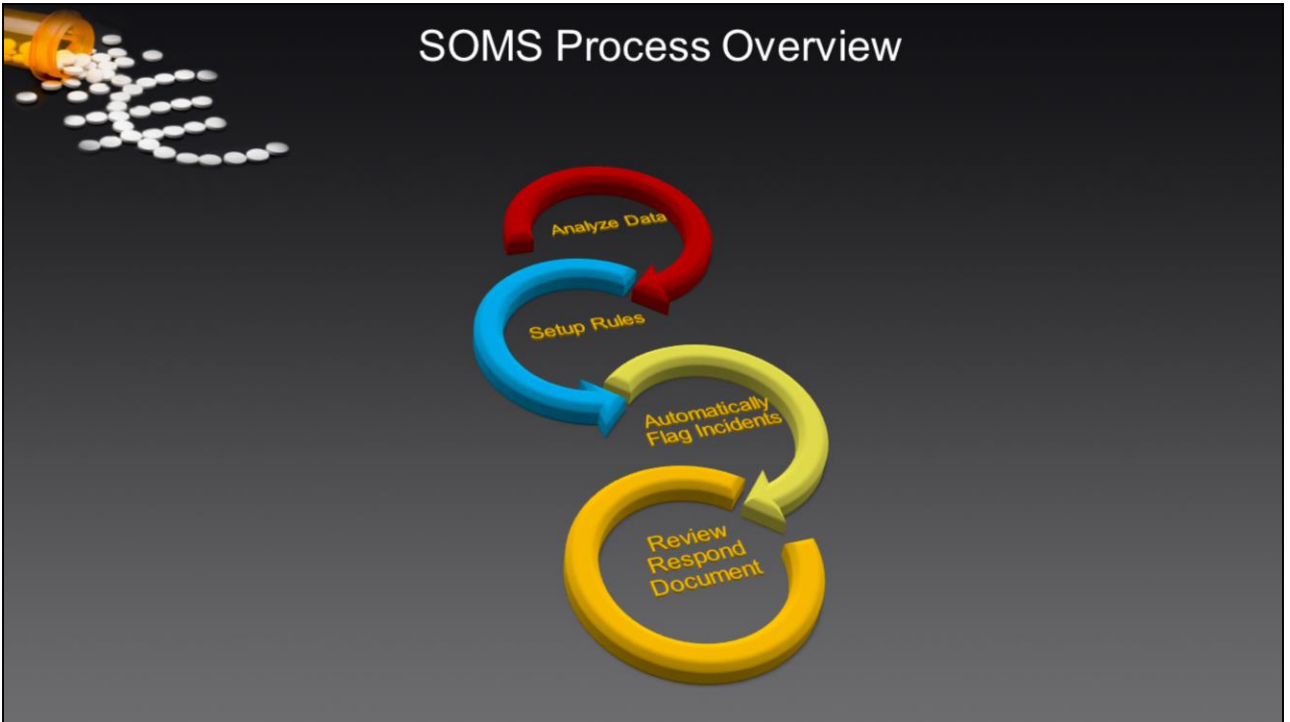
Integrated
Pharmaceutical
Compliance



The Systems House, Inc.

Software Tools for the Healthcare Supply Chain





Suspicious Order Monitoring System (SOMS)

The SOMS system provides the operators a system to identify suspicious orders of controlled substances and provides the tools to reports these instances.

The SOMS module is located directly off the Pharma menu.

The System is integrated into the MDS-Nx System and utilizes historical data across customers, peer groups and product groups to help you identify suspicious trends.

Once you have utilized the MDS Reporting Tools you can then setup rules

DEA Requirements

Question: What constitutes a Suspicious Order and how can Suspicious Orders be easily recognized?

Answer: The DEA has frequently been asked for guidance on what constitutes a suspicious order. The Suspicious Orders Task Force (SOTF) met in 1997 to

make recommendations to industry on recognizing suspicious orders. The following guidelines, contained in the Chemical Handlers Manual, are intended to assist chemical manufacturers, distributors, wholesalers and retailers to be alert to suspicious orders involving listed chemicals. Consistent application of these guidelines will help industry assist DEA in preventing the diversion of legitimate chemical products to illegal drug manufacturing and use. The guidelines are intended to apply to all aspects of commercial chemical manufacturing and distribution. It is important that the guidelines are applied to the totality of any particular circumstances. No individual indicator listed below is independently a suggestion that a given order is suspicious and/or reportable to DEA. Questions concerning potentially suspicious orders should be directed to the local DEA office.

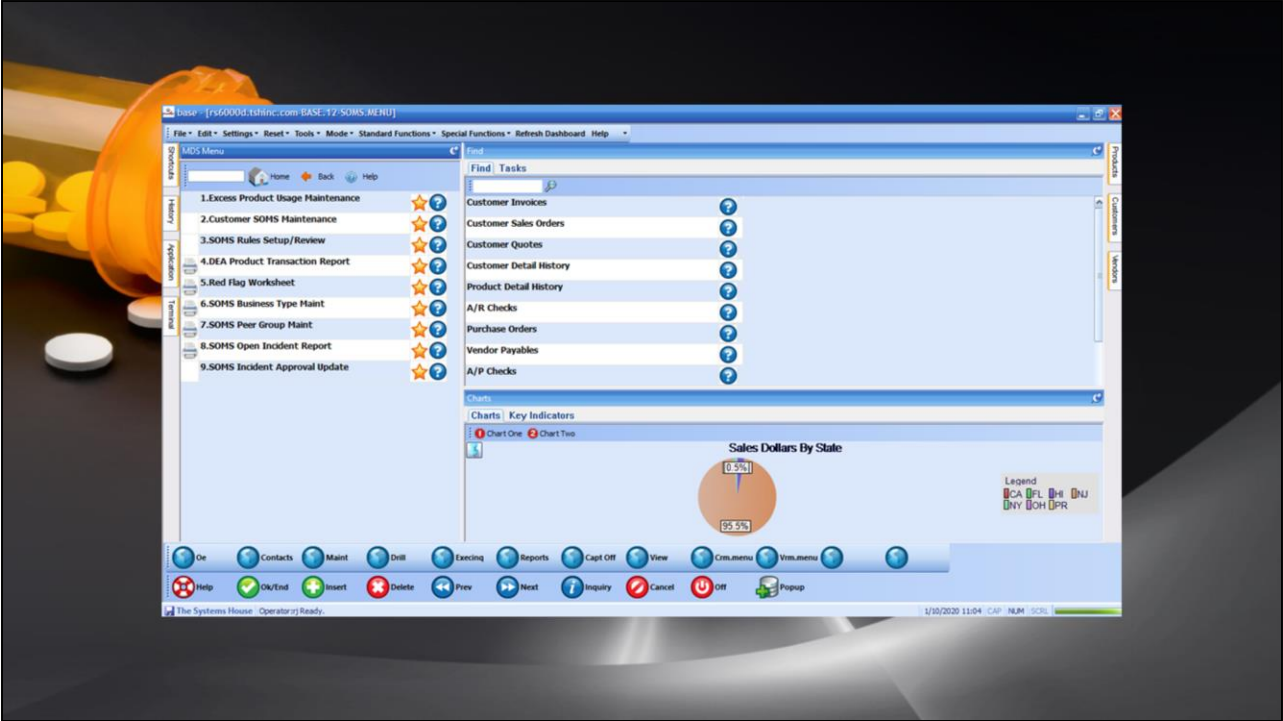
"Know Your Customer" Policy

It is fundamental for sound operations that handlers take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently, identify those transactions conducted by their customers that are suspicious in nature.

Some states have restrictions on distribution practices that are more stringent than the federal rules. The extent of compliance with state law is taken into consideration when civil, administrative, or criminal actions are under consideration.

It is required that any regulated person verify that a customer for List I products possesses a valid DEA registration or is exempt from that requirement.

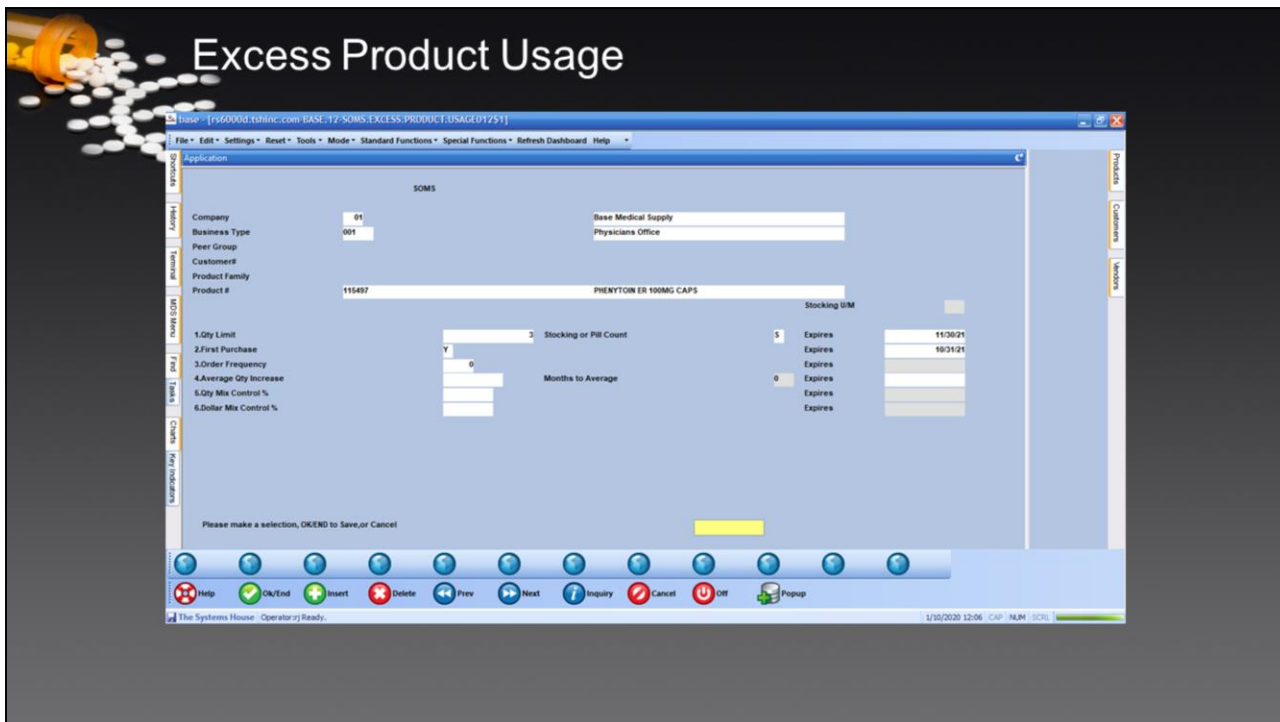
The granting of a DEA registration signals only a proper application, the establishment of the required records system, and the required security system at the time of the on-site inspection by DEA. The registration is not a confirmation of proper ongoing business practices and does not relieve the chemical handler of the responsibility to evaluate such transaction.



Suspicious Order Monitoring System (SOMS)

The SOMS system provides the operators a system to identify suspicious orders of controlled substances and provides the tools to reports these instances.

The SOMS module is located directly off the Pharma menu.



Excess Product Usage

The Excess Product Usage program contains one record for each customer/product that a customer may purchase.

This program provides the operator many different options for monitoring product usage:

Quantity Limit, First Purchase, Order Frequency, Average Quantity Increase, Quantity Mix Control Percent, and Dollar Mix Control.

Company – select your company.

The next three selections determine who the SOMS record is being assigned to:

Business Type – select the business type.

And/or

Peer Group – select the record of the peer group.

And/or

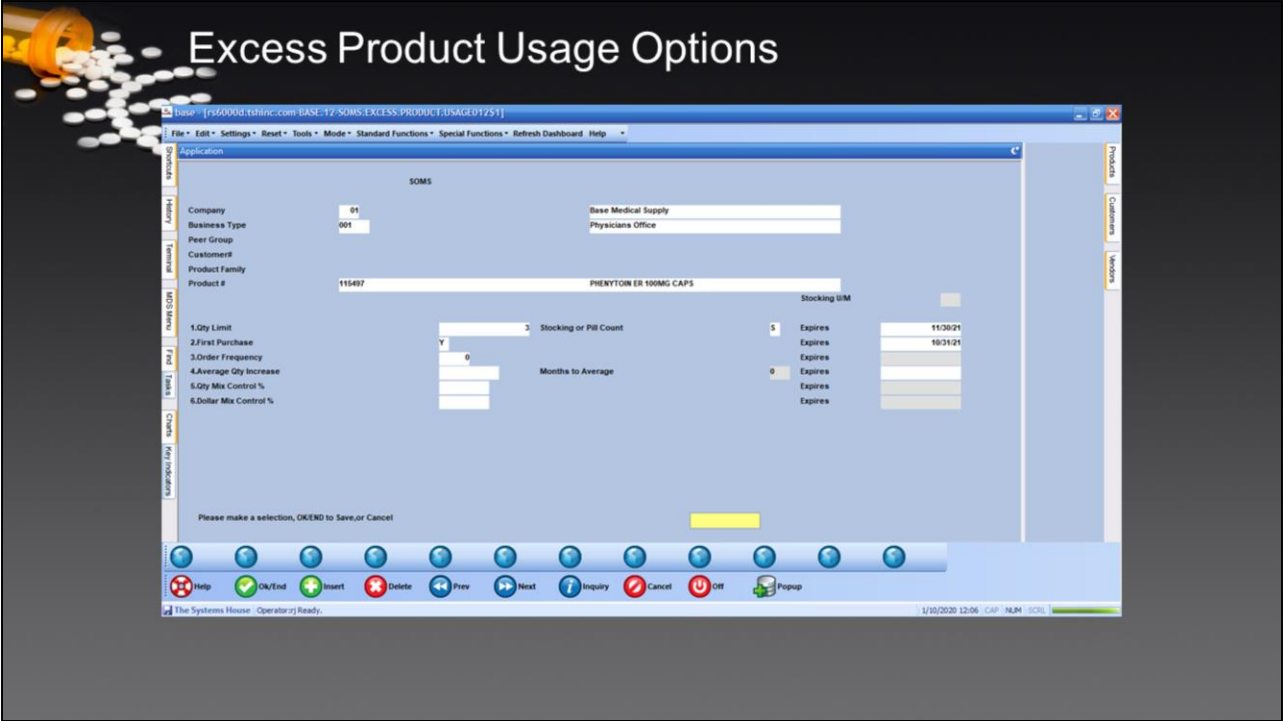
Customer# - select a specific customer.

Then select:

Product Family – select the specific product family.

And/or

Product# - select the specific product.



Excess Product Usage

The next portion is the detail of the rule you are creating.

Options:

Option #1 – Quantity Limit

Quantity Limit – set a specific quantity limit to be followed.

If a quantity is entered, next input whether the quantity limit is based on the stocking unit of measure, or total pill count.

Expires – enter the expiration date for this rule.

Option #2 – First Purchase

First Purchase – set this flag to “Y” when the product or family is purchased for the first time.

Expires – enter the expiration date for this rule.

Option #3 – Order Frequency

Order Frequency – input the order quantity to flag when the number of times ordered per month is greater than the order frequency.

Expires - enter the expiration date for this rule.

Excess Product Usage Addl Options

The screenshot displays the 'SOMS' application window. The title bar shows the URL: `https://[166000].tshinc.com:BASE:17/SOMS:EXCESS.PRODUCT.USAGE(17251)`. The menu bar includes: File, Edit, Settings, Reset, Tools, Mode, Standard Functions, Special Functions, Refresh Dashboard, Help. The interface is divided into several sections:

- Company Information:** Company (01), Business Type (001), Peer Group, Customer#, Product Family.
- Product Information:** Product # (115497), PHENYTON ER 100MG CAPS.
- Stocking U/M Table:**

Stocking U/M	Expires	Expires
5	Expires	11/30/21
	Expires	10/31/21
	Expires	
	Expires	
	Expires	
	Expires	
- Additional Options:**
 - 1.Qty Limit: 3
 - 2.First Purchase: Y
 - 3.Order Frequency: 0
 - 4.Average Qty Increase: Months to Average
 - 5.Qty Mix Control %
 - 6.Dollar Mix Control %

At the bottom, a status bar reads: 'The Systems House Operator Ready' and '1/30/2020 12:06 CAP NLM SOMS'.

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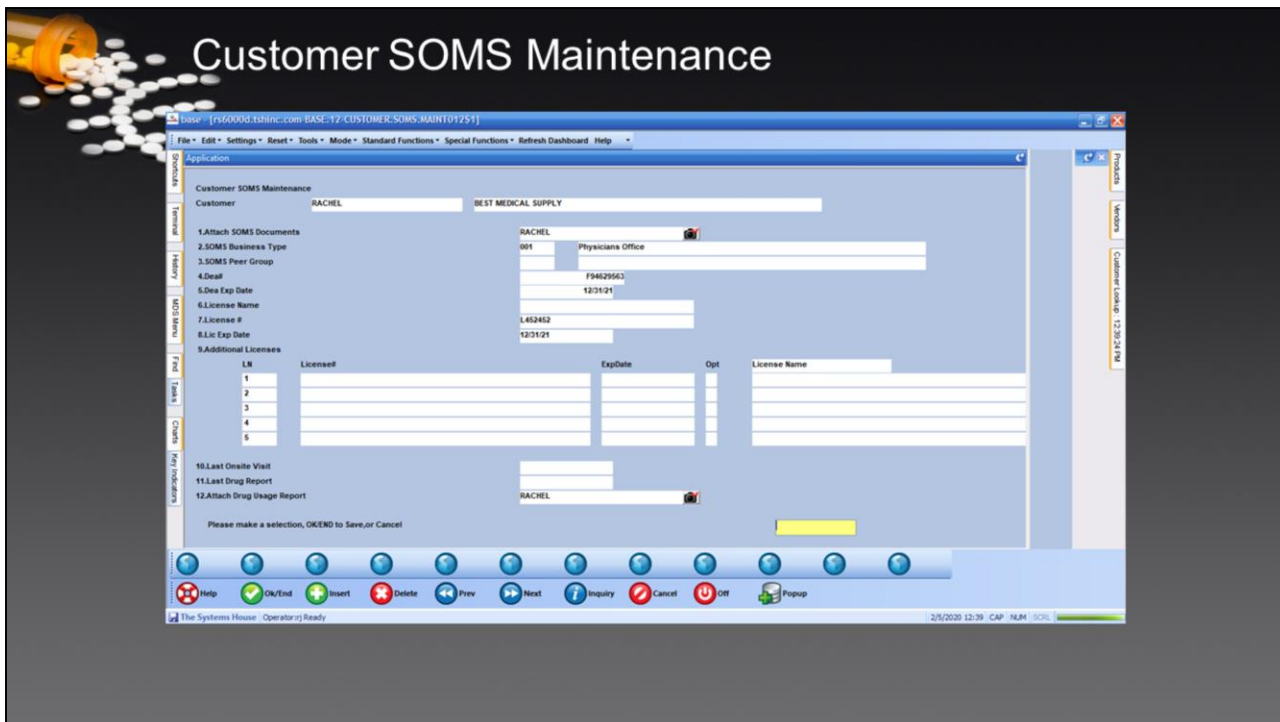
Dolla
amou

order. When the inputted amount is greater than this percent of the total dollar amount of the items on the order, the order will go on hold.

Expires - enter the expiration date for this rule.

Please make a selection, OK/END to Save, or Cancel

Click on any field (or input the field number and hit <ENTER>) to make a change. Click on the "OK/END" button to save the record. Click on the "CANCEL" button to exit the screen without saving.



Customer SOMS Maintenance

This maintenance allows for the entry of various information specific to the customer. Additionally, license information will be displayed, and can be updated directly in this maintenance.

Attach SOMS Documents – the operator can load any documents to this field relating to SOMS.

To load the data just click on the camera button and choose “Load a File or Image from a Folder”, then follow the prompts to select the file.

To retrieve a stored file, right click on the field and choose “Display” or “History”. By choosing “Display” the system will display the last document scanned. If “History” is selected, the operator can choose which document to display. See the Document Management documentation for more information.

SOMS Business Type – select a business type from the drop down.

SOMS Peer Group – select a peer group from the drop down.

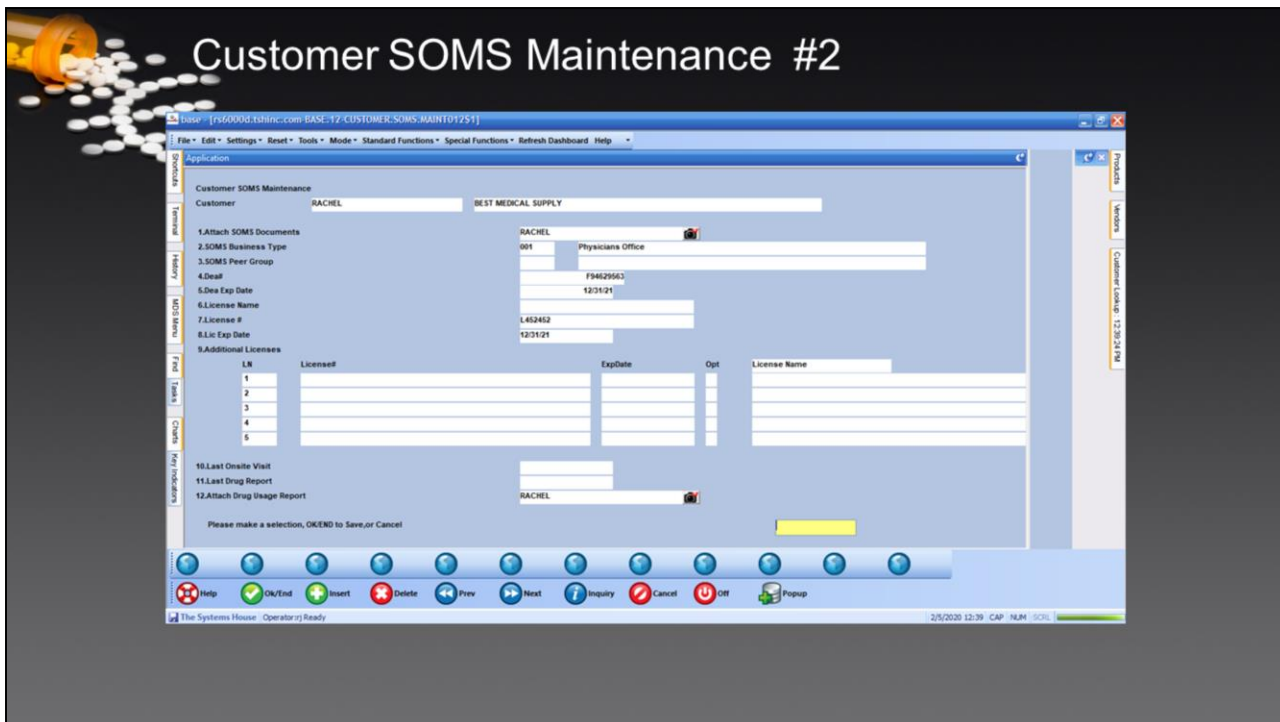
The following information is stored in the Customer Master record, if any changes are done here, the system saves it to the Customer Master record.

DEA# and Expiration Date

License Name

License# and Expiration Date

Additional Licenses



Customer SOMS Maintenance

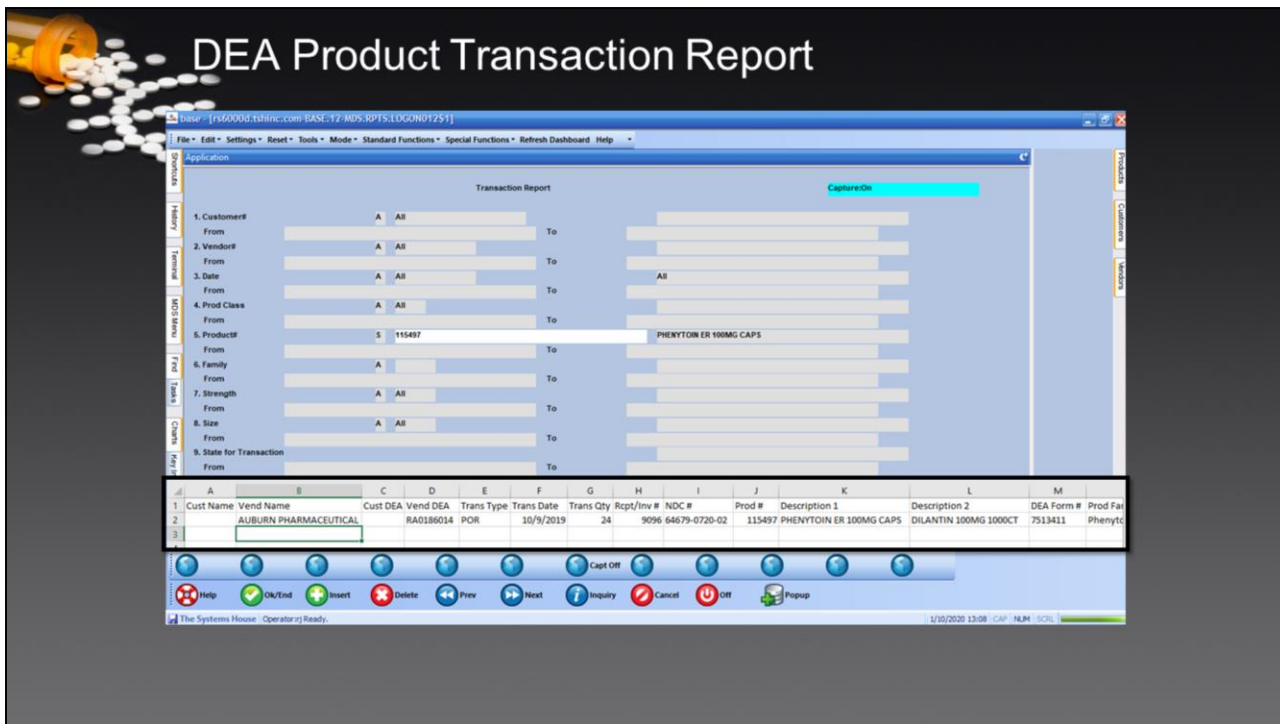
Last Onsite Visit – the operator can input the date of the last onsite visit to the customer site.

Last Drug Report = the operator can input the date of the last drug report received.

Attach Drug Usage Report – the operator can load a copy of the Drug Usage report. See above on how to load and retrieve.

Please make a selection, OK/END to Save, or Cancel

Click on any field (or input the field number and hit <ENTER>) to make a change. Click on the “OK/END” button to save the record. Click on the “CANCEL” button to exit the screen without saving.



DEA Product Transaction Report

This report, in Excel format, will show the operator all transactions for the criteria selected.

Selection Criteria:

Customer# - All customers, range of customers, or a specific customer

Vendor# - All vendors, range of vendors, or a specific vendor

Date – All dates, range of dates, or a specific date

Prod Class – All product classes, range of product classes, or a specific product class

Product# - All products, range of products, or a specific product

Family – All product families, range of product families, or a specific product family

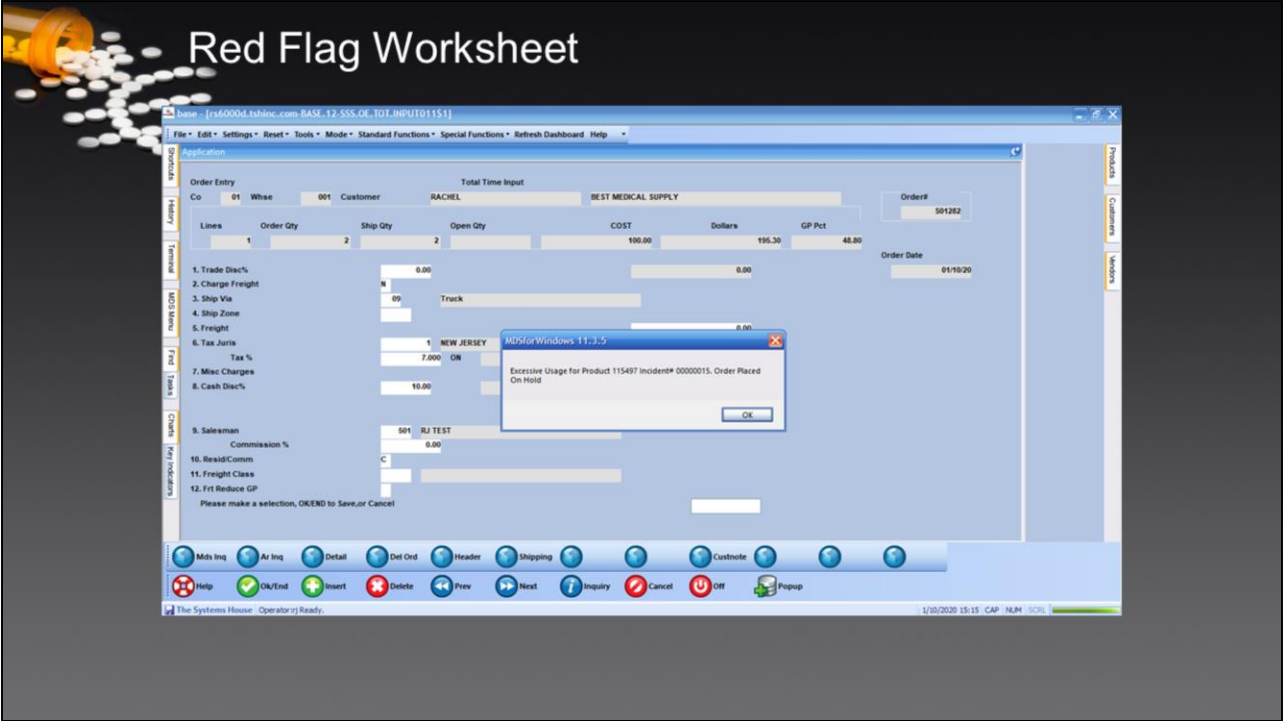
Strength – All product strengths, range of product strengths, or a specific product strength

Size – All product sizes, range of product sizes, or a specific product size

State for Transaction – All states, range or states, or specific states

Press <RETURN> to Process Report, Line# to Change, or ABORT

Hit <ENTER> to process the report, enter a line# and hit <ENTER> to make a change, or click on the "CANCEL" button to exit.



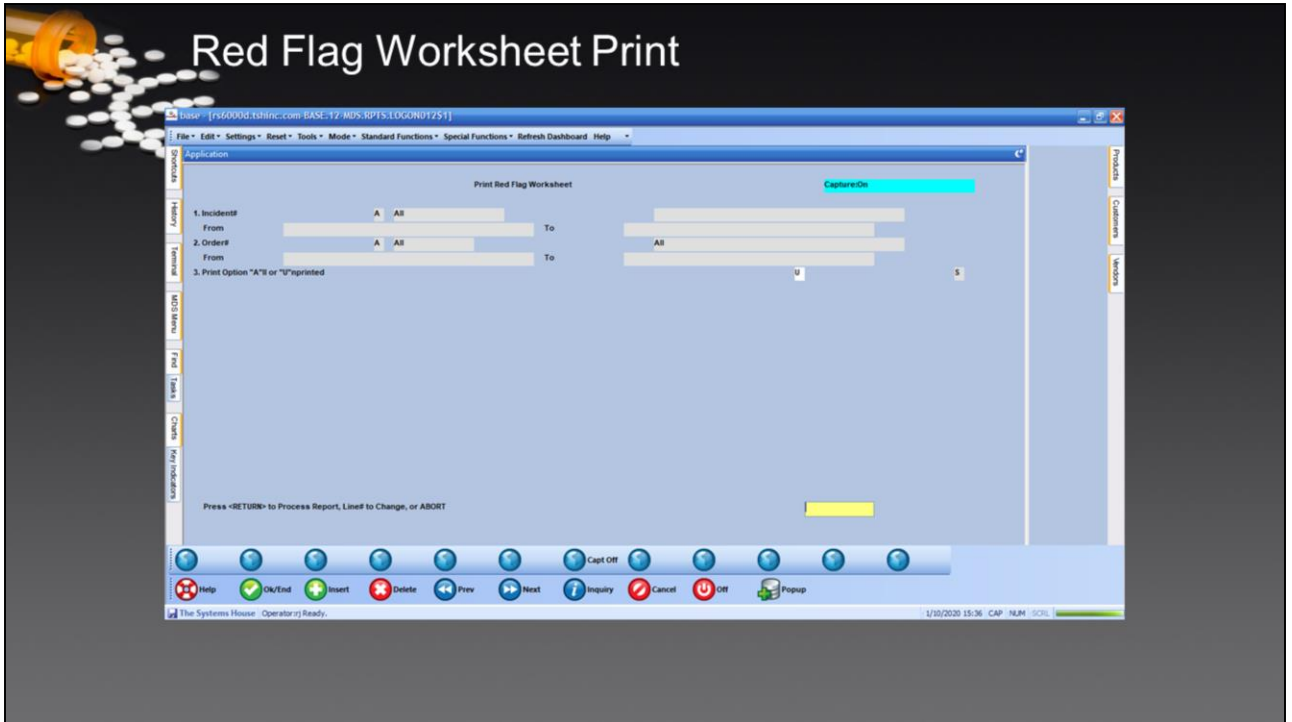
Red Flag Worksheet

This program will print a red flag worksheet for any incidents that were flagged due to failing a rule set in the Excess Product Usage program.

During order entry, if an item fails one of the SOMS rules, the operator will receive an error and the order will be placed on hold.

To move forward, an operator would then print the Red Flag worksheet(s) to review the incident and decide how to move forward.

This program will print a red flag worksheet for any incidents that were flagged due to failing a rule set in the Excess Product Usage program.



Red Flag Worksheet

Prompts:

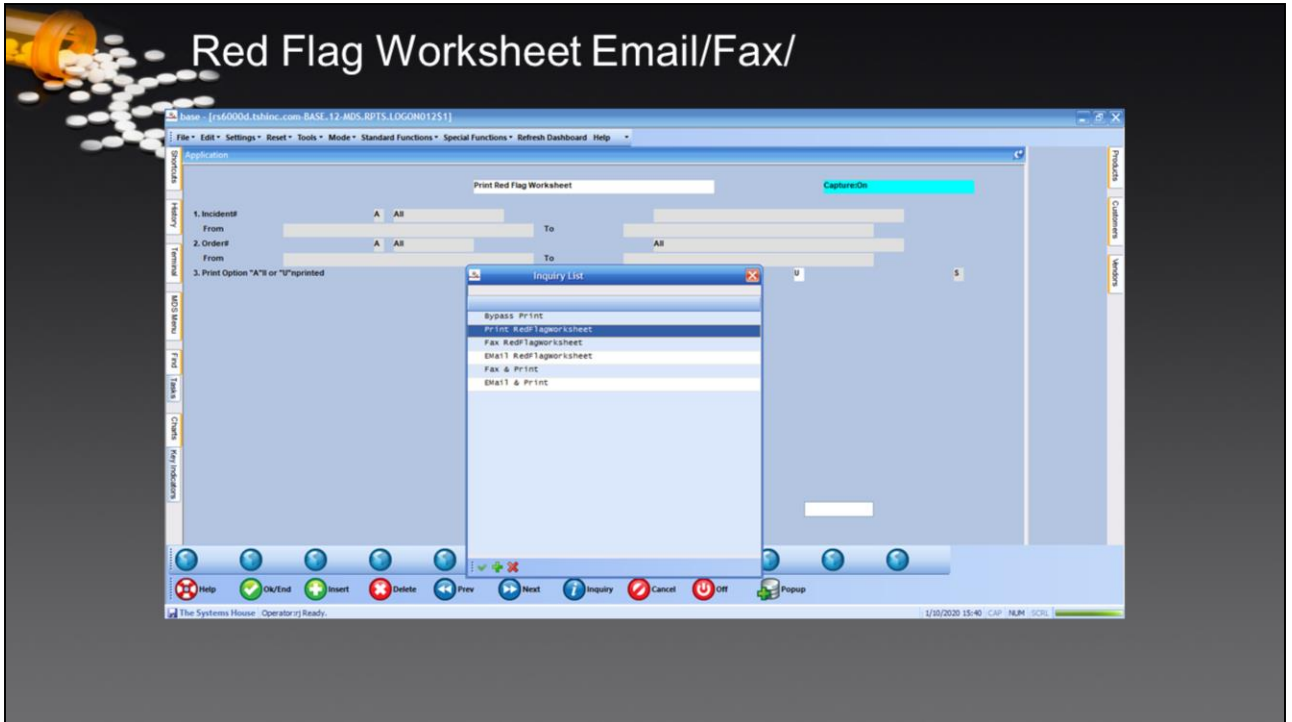
Incident# - All, Range, Specific, or Multiple.

Order# - All, Range, Specific, or Multiple.

Print Option “A” or “U” printed – If “A” is inputted, all worksheets will print, otherwise input “U” to only print those not printed yet.

Press <RETURN> to Process Report, Line# to Change, or ABORT:

Hit <ENTER> to continue.



Red Flag Worksheet

The options to print are:

Bypass Print – will skip the printing of the document.


Print RedFlagWorksheet – prints to the default printer.

Fax RedFlagWorksheet – faxes the document.

Email RedFlagWorksheet – emails the document.

Fax & Print – does both: faxes and prints the document.

Email & Print – does both: emails and prints the document.



Example Red Flag Worksheet

Red Flag Worksheet

MDS Order # 01S01282 Incident # 00000015 Customer # RACHEL

This incident report was created for the following reason:
 115497 on Order 01S01282 for 2 BT has been ordered for the first time on line# 1. SOMS Incident 00000015 created.
 Please fill out the form below and if required please contact customers and or your DEA office.

- Location** - Are they located in an area or state with a reputation for a high rate of CS diversion? (i.e. Florida, Texas, Nevada, Ohio)
- Quantity** - Are they purchasing "Trinity Drugs" in quantities or at a frequency that raises concern?
- Combination** - Are they purchasing quantities of regulated drugs, while ordering few if any non-regulated drugs?
- Payment Terms** - Do they request C.O.D/Cash and/or are they a credit risk?
- Next Day Delivery** - Do they order CS drugs frequently and request or demand next day delivery?
- Deviation in Buying** - Does their frequency and order amount increase/decrease for CS/NON-CS drugs?
- Contact Information** - Are they giving you personal information instead of business information?
- Evasive Behavior** - Are they avoiding or refusing questions regarding increased purchases?
- Delivery Change** - Do they frequently request delivery to different addresses?
- Usage** - Have they turned in a 90 day usage report with suspicious or unusual amounts of cs dispensed?

	Document Name	Document Date
Supporting Documentation		

Red Flag Worksheet



Compliance Recommendations

Limit Quantity Sold _____ Sell Only Non-controlled Substances _____
Request Additional Info _____ Other (Explain) _____

Approval by Senior Management required for the following reasons Stop Sales Report to DEA

Compliance Approval

Name (Print) _____ Title _____
Signature _____ Date _____

Senior Management Approval (If Required)

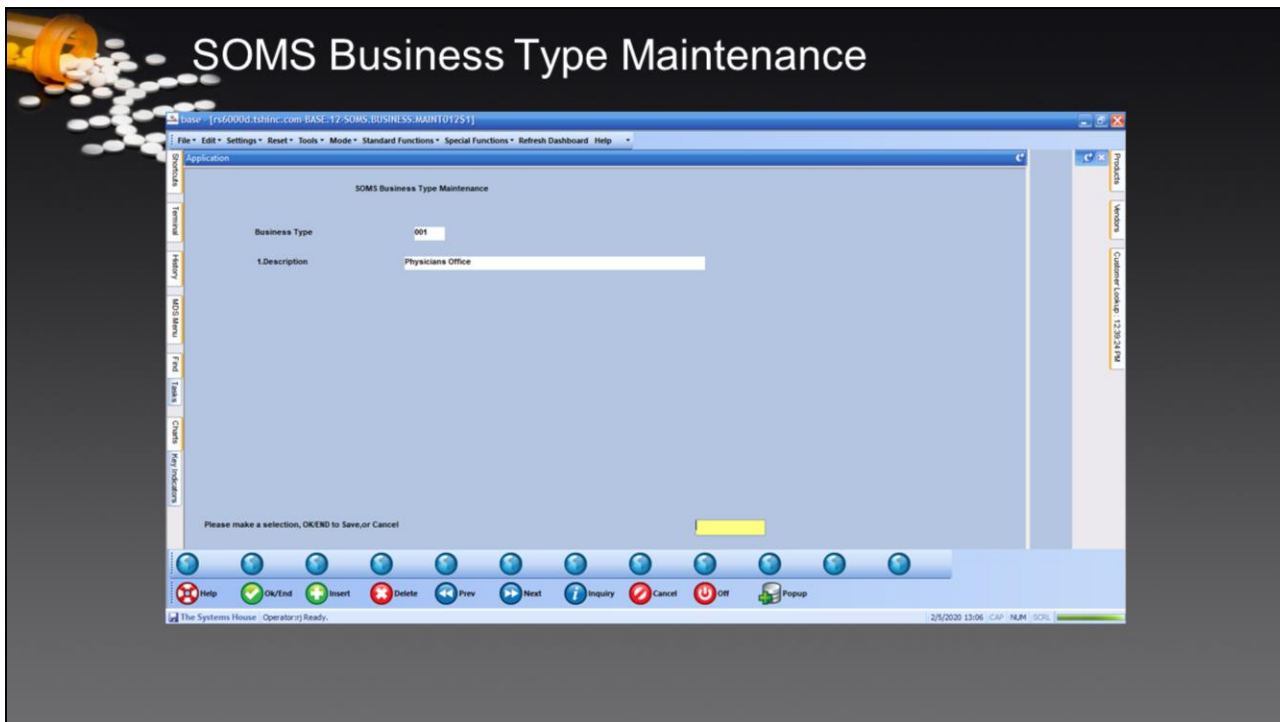
Name (Print) _____ Title _____
Signature _____ Date _____

Service Rep or Sales Person Signature

Name (Print) _____ Title _____
Signature _____ Date _____

Additional Comments _____

Red Flag Worksheet



SOMS Business Type Maintenance

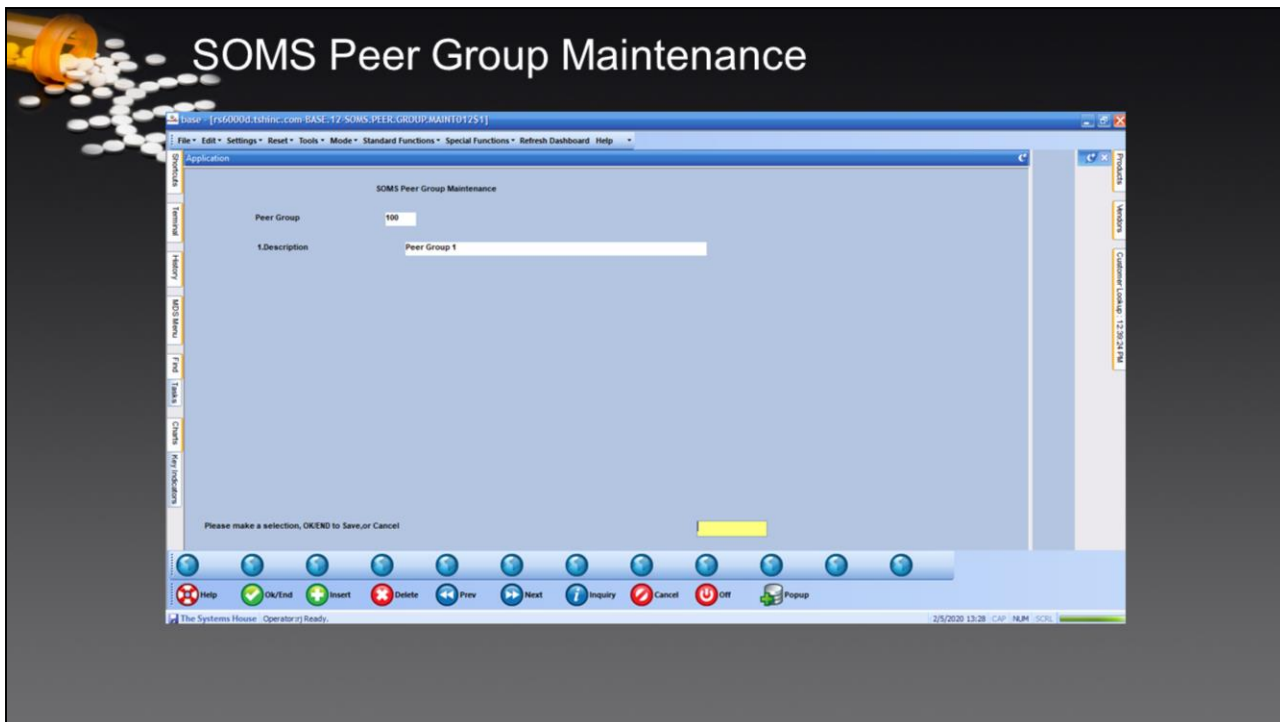
A business type can be created to group your customers

Business Type – Input or select the Business Type.

Description – If this is a new business type, input the business type. If this business type exists, the description will display and can be modified.

Please make a selection, OK/END to Save, or Cancel

Click on any field (or input the field number and hit <ENTER>) to make a change. Click on the “OK/END” button to save the record. Click on the “CANCEL” button to exit the screen without saving.



SOMS Peer Group Maintenance


A peer group can be created to group your customers

Peer Group – Input or select the Peer Group.


Description – If this is a new peer group, input the peer group. If this peer group exists, the description will display and can be modified.

Please make a selection, OK/END to Save, or Cancel

Click on any field (or input the field number and hit <ENTER>) to make a change. Click on the “OK/END” button to save the record. Click on the “CANCEL” button to exit the screen without saving.



SOMS Open Incident Report



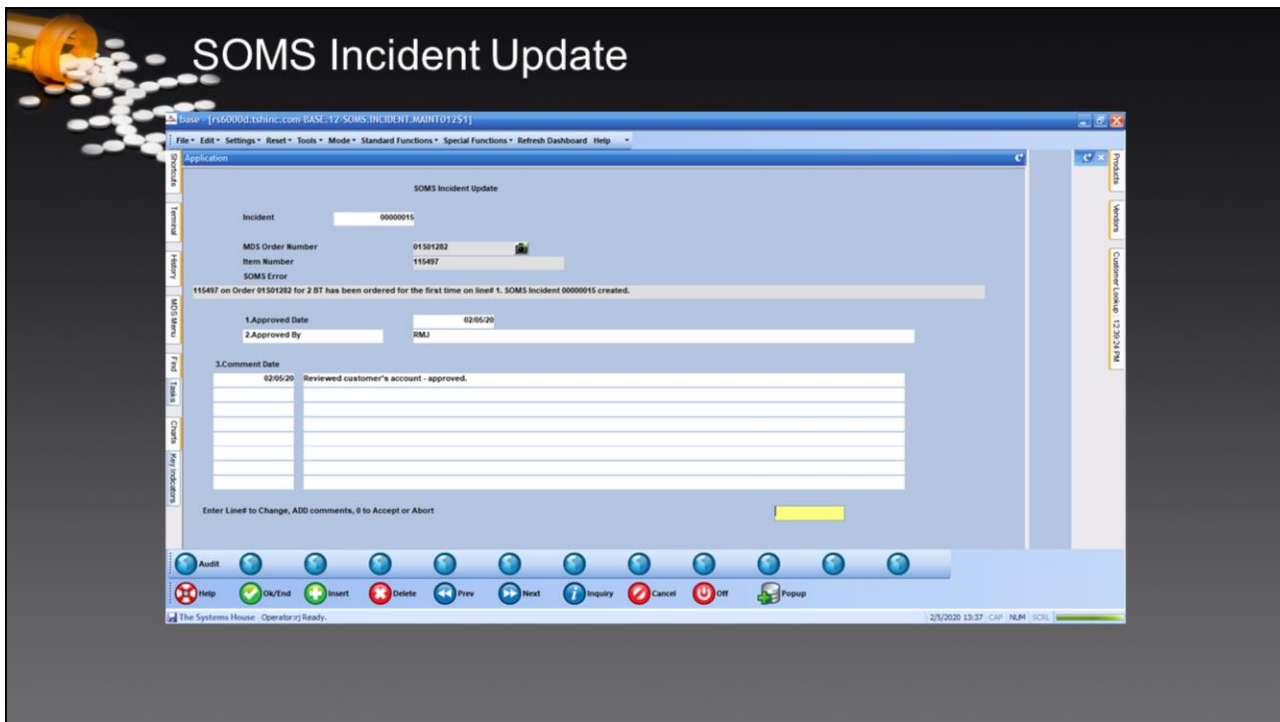
MDS SOMS OPEN INCIDENT REPORT 02/05/20 13:34:08

Page 2 of 2

INCIDENT	ORDER	ITEM	PRINTED	ERROR
00000011	01S00873	00409-1463-01	1/10/2020	00409-1463-01 on Order 01S00873 for 3 EA has been ordered for the first time on line# 1. SOMS Incident 00000011 created.
01S01123				
00000013	01S01123	15270	1/10/2020	15270 on Order 01S01123 for 8 EA exceeds the Qty. Limit of 3 on line# 1. SOMS Incident 00000013 created.
00000014	01S01123	15270	1/10/2020	15270 on Order 01S01123 for 8 EA has been ordered for the first time on line# 1. SOMS Incident 00000014 created.
01S01282				
00000015	01S01282	115497	1/10/2020	115497 on Order 01S01282 for 2 BT has been ordered for the first time on line# 1. SOMS Incident 00000015 created.

SOMS Open Incident Report

This report will show all open incidents, along with the reasoning for the issue.



SOMS Incident Update

In this program, the operator updates the incident with notes, backup documentation, and an approval

After the Incident is approved, the system will update the audit trail showing the approval. However, the order will still need to be removed from Manual Order Hold

Incident – input or select the incident number from the drop down

MDS Order Number – the order number is displayed

Item Number – the item number is displayed

SOMS Error – a detailed reason for the order being placed on hold is displayed

Approved Date – input or select the approved date from the calendar

Approved By – input the operator name or initials of who is approving the incident.

Comment Date – input or select the approved date from the calendar.
Additionally, the operator can input notes.

Enter Line# to Change, ADD comments, 0 to Accept or Abort

Click on any field (or input the field number and hit <ENTER>) to make a change. Type “ADD” to add additional comments. Click on the “OK/END” button to save the record. Click on the “CANCEL” button to exit the screen without saving.

Where to Get More Information

- To contact support, call 973-777-8050 or fax 973-777-1483
- To access The Systems House's website: www.tshinc.com