

Integrated Clinical Services Procedure 340B Program Procedures

EFFECTIVE DATE: 3/16/20

PROCEDURE TITLE:

Stock Transfer During Covid-19

To be reviewed every three years by: 340B Steering Team REVIEW BY: 3/16/23

PROCEDURE

This Procedure is intended to identify how stock will be transferred between Trinity Health Ministries during the Covid-19 Pandemic.

SCOPE/APPLICABILITY

This Procedure is intended to apply to all Trinity Health 340B Disproportionate Share Hospital (DSH), Critical Access Hospital (CAH), Sole Community Hospital (SCH), and Rural Referral Center (RRC) programs.

DEFINITIONS

Ministry means a first tier (direct) subsidiary, affiliate, or operating division of Trinity Health that maintains a governing body that has day-to-day management oversight of a designated portion of Trinity Health System operations. A ministry may be based on a geographic market or dedication to a service line or business. Ministries include Mission Health Ministries, National Health Ministries, and Regional Health Ministries.

Policy means a statement of high-level direction on matters of strategic importance to Trinity Health or a statement that further interprets Trinity Health's governing documents. System Policies may be either stand alone or Mirror Policies designated by the approving body.

Procedure means a document designed to implement a policy or a description of specific required actions or processes.

Regional Health Ministry ("RHM") means a first tier (direct) subsidiary, affiliate or operating division of Trinity Health that maintains a governing body that has day-to-day management oversight of a designated portion of Trinity Health System operations and includes at least one hospital.

Standards or Guidelines mean additional instructions and guidance which assist in implementing Procedures, including those developed by accreditation or professional organizations.

Subsidiary means a legal entity in which a Trinity Health Ministry is the sole corporate member or sole shareholder.

RESPONSIBLE DEPARTMENT

Further guidance concerning this Procedure may be obtained from the System Office 340B Program

APPROVALS

Initial Approval: 5/1/20

Subsequent Review/Revision(s): none

During the Covid-19 Pandemic, Trinity Health is actively tracking the available utilization of drugs that have been identified as being, at times, in critical shortage, including but not limited to:

Albuterol Inhaler

Atracurium Inj

Azithromycin Inj

Cistatricurium Inj

Dexmedetomidine Inj

Etomidate Inj

Fentanyl Inj

Hydromorphone Inj

Hydroxychloroquine tab/cap

Ketamine Inj

Midazolam Inj

Norepinephrine Inj

Pancuronium Inj

Propofol Inj

Rocuronium Inj

Succinylcholine Inj

Vecuronium Inj

Trinity Health is tracking days-on-hand of these critical drugs three times a week. Locations that are below 8 days-on-hand are contacted to see if they are unable to purchase product from alternative sources. Sites that are unable to obtain product and are in critical need well be provided product from other Ministries with an excess of product.

To maintain compliance with the prohibition of diversion of 340B drugs, stock provided from a 340B DSH Ministry will always come from their neutral virtual inventory. This stock will be transferred to another Ministry, and the Wholesale Acquisition Cost (WAC) cost of that drug will be charged back to the receiving Ministry. Stock provided from a 340B CAH, SCH, or RRC Ministry will be provided from Group Purchasing Organization (GPO) stock, and the GPO cost of that drug will be charged back to the receiving Ministry.

If a 340B Ministry that must comply with the GPO prohibition is in critical need of a drug, stock should be provided from the neutral virtual inventory from another 340B DSH hospital whenever possible and charged at WAC cost. Should neutral inventory from another 340B Ministry be unavailable, stock from a non-340B entity may be transferred to meet the critical need. This stock transfer will be documented, and when possible, the receiving Ministry will replace the drug back to the sending Ministry through a WAC purchase of the same drug that is sent to the original sending Ministry. When it is not possible for the receiving Ministry to make a WAC purchase to replace the transferred stock, the WAC cost will be charged to the receiving Ministry.

Transferring Ministry	Receiving Ministry	Original Purchase Account	Charge back price
340B DSH	340B DSH	Virtual WAC	WAC
340B DSH	340B non-DSH	Virtual WAC	WAC
340B DSH	Non-340B	Virtual WAC	WAC
340B non-DSH	340B DSH	Virtual GPO; should be last resort	DSH should replace with WAC purchase; WAC as last resort
340B non-DSH	340B non-DSH	Virtual GPO	GPO
340B non-DSH	Non-340B	Virtual GPO	GPO
Non-340B	340B DSH	GPO; should be last resort	DSH should replace with WAC purchase; WAC as last resort
Non-340B	340B non-DSH	GPO	GPO
Non-340B	Non-340B	GPO	GPO

Product Transfer Process:

The Product Transfer is the result of the System Office being contacted by a Ministry that is low on a product or through report analysis determination of a potential future shortage. System Office will contact other Ministries with potential available inventories and facilitate a product transfer.

- System Office will provide a Product Transfer form to the shipping Ministry that includes
 all necessary contact information for the receiving Ministry. An email is sent from the
 shipping Ministry to the receiving Ministry Pharmacy Director with a copy to Meena
 Rupani MEENA.RUPANI@trinity-health.org and Gary Freeman
 Gary.Freeman002@trinity-health.org defining the following for each drug shipped:
 - o Shipping date
 - Shipping method
 - o Tracking number
 - o Drug name
 - o Dosage/strength/size
 - Manufacturer
 - o NDC Number
 - o Total quantity shipped
 - Unit price or total cost
 - o If this is a controlled substance The DEA #
- This email is either carbon copied (cc'd) or forwarded to Tim Morgan
 <u>Timothy.Morgan@trinity-health.org</u> responsible for monitoring the product transfer
 process.
- The information supplied by the shipping ministry is entered in the Product Transfer Log and the following information is added:
 - o PeopleSoft account numbers for the shipping and receiving locations.
- The receiving Ministry will send an Email to the shipping Ministry Pharmacy Director and copy Meena and Gary and when the transferred product is received noting its receipt.
 - If this is a Schedule II controlled substance DEA form 222 must be completed by the receiving Ministry.

Month-End Close Process

- When the total amount of the Product Transfers reaches a material amount as defined by SCM Finance Management the Log will be closed for that period.
- A report will be generated of the transactions and saved in the file with the Product Transfer Log as a reference and back-up.
- A copy of the report will be provided to Pharmacy Sourcing.

Ministry	Location	Classification
MercyOne Primghar	Primghar, Iowa	non-DSH
MercyOne - New Hampton	New Hampton, Iowa	non-DSH
Mercy Fitzgerald Hospital (MCMC)	Darby, Pennsylvania	DSH
Mercy Medical Center - Springfield	Springfield, Massachusetts	DSH
St. Alphonsus Medical Center - Baker City	Baker City, Oregon	non-DSH
St. Alphonsus Medical Center - Ontario	Ontario, Oregon	non-DSH
St. Francis Hospital - SFDE	Wilmington, Delaware	DSH
Holy Cross Hospital	Silver Spring, Maryland	DSH

Lakeshore Hospital	Shelby, Michigan	non-DSH
Mercy Health Partners	Muskegon, Michigan	DSH
St. Alphonsus Medical Center - Nampa	Nampa, Idaho	DSH
MercyOne North Iowa	Mason City, Iowa	DSH
St. Alphonsus Regional Medical Center	Boise, Idaho	DSH
St. Mary's Health Care	Grand Rapids, Michigan	DSH
Mercy Hospital & Medical Center	Chicago, Illinois	DSH
Loyola University Hospital	Maywood, Illinois	DSH
Saint Agnes Medical Center	Fresno, California	DSH
St. Joseph Mercy Oakland	Pontiac, Michigan	DSH
St. Francis	Trenton, New Jersey	DSH
MercyOne- Clinton	Clinton, Iowa	DSH
Mount Carmel St. Ann's	Westerville, Ohio	DSH
Saint Francis Hospital and Medical Center	Hartford, Connecticut	DSH
MercyOne Waterloo	Waterloo, Iowa	DSH
MercyOne Oelwein	Oelwein, Iowa	non-DSH
Holy Cross Germantown Hospital	Germantown, Maryland	DSH
Nazareth Hospital	Philadelphia, Pennsylvania	DSH
Saint Mary's Hospital	Waterbury, Connecticut	DSH
St. Mary's Health Care System	Athens, Georgia	non-DSH
Mount Carmel Health	Columbus, Ohio	DSH
MercyOne Dyersville	Dyersville, Iowa	non-DSH
MercyOne Siouxland	Sioux City, Iowa	non-DSH
MacNeal Hospital	Berwyn, Illinois	DSH
MercyOne Oakland	Oakland, Nebraska	non-DSH
Samaritan Hospital	Troy, New York	DSH