

Drug Supply Chain Security Act (DSCSA)

Frequently asked questions

- 01 DSCSA general questions and readiness
- 02 Receiving and returns
- 03 Electronic Product Code Information Services (EPCIS)
- 04 Global Location Number (GLN)
- 05 Small dispenser exemption and waivers, exceptions, exemptions (WEE)

DSCSA general questions and readiness

What is DSCSA?

DSCSA, or Drug Supply Chain Security Act is a federal law that went into effect on November 27, 2023, with a 1-year stabilization period that enhances the unit level tracing capabilities through inbound receiving, outbound sending, and return transaction information at the distribution level for pharmaceuticals. In accordance with this legislation, all prescription product moving through the entire supply chain must be tracked.

Why is DSCSA needed?

The legislation was passed to help prevent the introduction of counterfeit pharmaceuticals and enable enhanced tracking of product from manufacturer to the patient.

What does DSCSA trace?

DSCSA traces National Drug Codes (NDCs), container size, transaction date, number of containers, lot number, expiration dates, serial numbers and name and addresses of previous and subsequent owners of the product.

What is Cencora/DSCSA?

Our operational teams have been diligently working for years and will maintain our commitment and focus to be fully prepared for DSCSA by this November. In an effort to prioritize patient access as the DSCSA stabilization period comes to an end, Cencora has submitted a Waiver, Exception, or Exemption (WEE) application for certain products. This application does not indicate that Cencora is not ready or prepared for full DSCSA compliance; rather, this WEE covers any National Drug Codes (NDCs) for which Cencora is not receiving full serialized data from the manufacturer to ensure patient access for those products. We remain actively engaged with industry partners and the FDA to navigate DSCSA implementation and enforcement.

When does the FDA intend to take action to enforce DSCSA?

The FDA has announced it does not intend to act on the enforcement of DSCSA until November 27, 2024. While the DSCSA law still goes into effect this November, this creates a 1-year stabilization period that allows manufacturers, distributors, dispensers, and all trading partners within the pharmaceutical supply chain additional time to refine systems and processes necessary to maintain compliance under DSCSA. The FDA has confirmed and communicated that no additional extensions will be granted. However, Waiver, Exception, and Exemption (WEE) requests are available to mitigate some of these risks as the official stabilization period ends.

DSCSA general questions and readiness

What does this mean for Cencora?

While the FDA has delayed DSCSA enforcement for one year to November 27, 2024, they have publicly said this is a “stabilization period” and does not mean the industry can stop working towards full compliance. Our business will proceed as planned to be fully prepared by this November when the law goes into effect and use this period to ensure our data and processes are mature for the eventual November 2024 date. Our operational teams have been working for years to prepare our business for DSCSA. That work will not stop.

What does this mean for dispensers?

Continue to be aware of and prepared for DSCSA. This twelve-month period between DSCSA's effective date and enforcement date provides more time for education, understanding, preparation, and stabilization. In addition to the stabilization period, the FDA is granting exemptions from certain DSCSA requirements to small dispensers until November 27, 2026. A small dispenser is defined as a company with 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians as of November 27, 2024. If you qualify for the small dispenser exemption or have submitted a Waiver, Exception, or Exemption (WEE) application, the new returns process will still apply this November, meaning dispensers must track serial numbers for every return to remain compliant.

What does this mean for manufacturers?

DSCSA traces National Drug Codes (NDCs), container size, transaction date, number of containers, lot number, expiration dates, serial numbers and name and addresses of previous and subsequent owners of the product.

What is Cencora/DSCSA?

This enforcement delay now gives Cencora (formerly AmerisourceBergen) additional time to ensure we are stable with receiving all manufacturers serialized data for 100% of products to prevent potential quarantines. Despite manufacturers having until November 2024 to be fully DSCSA compliant, we will continue to assist manufacturer trading partners achieve compliance by providing timely feedback on respective DSCSA transactions and establishing milestones to keep moving forward. We are committed to moving the supply chain forward in this transformative initiative and will be collaborating with both HDA and FDA during established check-ins to ensure the broader industry continues to progress and does not slow down.

Will there be more information on the stabilization period?

We continue to meet with industry partners and the FDA surrounding DSCSA and its enforcement. More information will be provided as it becomes available.

DSCSA general questions and readiness

Will the Cencora name change impact DSCSA transactional documents?

We have always treated DSCSA transactions at the corporate level, not at the individual business unit level. The FDA even acknowledged this practice in their DSCSA guidance on authorized trading partners. Because AmerisourceBergen Corp. is no longer, we have changed our DSCSA documents (both inbound and outbound) to reflect the new legal entity of Cencora Inc. You can continue to use this as-is, given there is no requirement that our DSCSA TI match the invoice or other customer facing documents.

Where can I find a list of what items are exempt from DSCSA?

A list of exempt items can be found in resources in ABC Order and ABC Central.

If I am a physician, how do I handle interoffice transfers?

Physicians do not need to do anything different for interoffice transfers as intercompany transactions are exempt from the DSCSA.

Do the transfer rules change for pharmacy-pharmacy transfers?

The returns process will change if the product is transferred from one location to another. If product is moved from location A to location B, location B will not be able to return the product **unless location B has access to the invoice orders for the account at location A**. Otherwise, we will not deem the product as saleable because we will have no record of shipping that product to location B.

If I, as a dispenser, shares a product with another dispenser not associated with my account, how is that tracked? Will the DEA audit this?

If you receive product shipped from us, then sell that product to another location, you will need to keep a record of that transaction like any wholesaler's DSCSA requirements as this becomes a Transfer of Ownership.

DSCSA general questions and readiness

What are the steps I should take as a customer?

This legislation will be important for you when it comes to returns specifically and ensuring your product is correct as you receive shipments.

Who does DSCSA impact?

DSCSA impacts manufacturers, distributors, and all “dispensers” which is any provider in a health system, hospital, community or specialty pharmacy, or independent community practice dispensing or administering pharmaceuticals that require enhanced unit level tracking per DSCSA definition.

Are there any video resources regarding DSCSA and its impact?

Yes, we currently have two videos available on www.amerisourcebergen.com/dscsa that can assist you in understanding DSCSA and its impact.

What if I have additional questions about DSCSA?

We encourage you to review the resources on www.amerisourcebergen.com/dscsa. We also have recordings of Q&A session webinars available to review in ABC Central under the Knowledge & Enrollment Center. If you have any additional questions, please email SecureSupplyChain@amerisourcebergen.com and we will work with you to answer any questions you may have.

Does DSCSA apply to future antibiotics orders?

Yes, the DSCSA will apply for all Rx products including antibiotic orders.

How should we handle items that are categorized differently at the state and federal levels? For example, Item A is considered an over the counter (OTC) item in most states, which would mean it is exempt from DSCSA. However, in Texas, Item A is categorized as a C5 Rx item, which would mean it is not exempt.

Because DSCSA is a federal statute, we only consider how the drug is classified at the federal level. If a drug is considered OTC by the FDA, but one state classified it as Rx Only, it is considered OTC for purposes of DSCSA. Additionally, any items purchased on AmerisourceBergen Marketplace (ie consumer products and general merchandise) are exempt from DSCSA.

DSCSA general questions and readiness

Should I consider creating and holding standard operating procedures for DSCSA?

Yes, you should consider establishing processes and procedures to investigate and properly handle suspect and illegitimate drugs.

Are there any other requirements to ensure a 340B Contract Pharmacy and the Covered Entity are compliant with DSCSA?

We will require a Transactional Data Agreement to be on file that allows both the Contract Pharmacy and the Covered Entity to have access to the DSCSA data in compliance with regulations.

Receiving and returns

What changes in the receiving process?

There is no requirement to change your existing receiving process.

Will I be required to scan every unit they receive?

It is not a requirement of the DSCSA to scan every unit you are receiving. Scanning is also not a requirement of the law.

Will we be scanning each individual bottle or tote?

AmerisourceBergen will be aggregating serial numbers to the tote so that if you receive an EPCIS data file then you can simply scan the tote once and infer all the serial numbers contained within the tote. You can also scan each individual item if preferred.

How are shortages handled with respect to DSCSA?

For shortages, please call Customer Service and file a claim. The claims process in ABC Order is also being updated to assist in identifying the serial number(s) that was not received.

Will there be DSCSA verifications when we get orders from other ABC locations (i.e. Dropped Shipped)?

The industry is currently working through the Drop Ship process and will communicate that once a formal process has been completed.

Will I have to do anything differently when receiving product into a pharmacy? If so, will their pharmacy software help with that? Will there be an additional cost?

You are not required to change anything about their current inbound receiving process. However, you can improve efficiencies in receiving and verification with a DSCSA solution. Implementing a DSCSA solution is an additional cost on their business as they are third party products.

Receiving and returns

Does an independent retail pharmacy need to scan Rx items upon receipt?

Scanning is not required for customers upon receipt. It is an option and there are vendors in the market who will work with dispensers to help receive serialized data electronically so that they can scan upon receipt for verification. You will also have the ability to download your EPCIS data report through the reporting module in ABC Order. You can then manually/visually review these reports against the received physical inventory as needed to meet compliance.

Will I be able to return product purchased before the effective date in November 2024 and do not have the new required tracking?

With the stabilization period implemented by the FDA, there are no changes to the returns process until November 27, 2024. You will be able to return product purchased before November 2024 for a limited period of time after the DSCSA stabilization period ends. When creating a return, if you select an invoice for a product purchased before DSCSA's effective date, you will be able to follow our current returns policy as it is today, pre-DSCSA.

After DSCSA goes into effect, if I move to a new distributor, what is the process for returning product that was purchased through their previous distributor?

Customer Care will download all relevant DSCSA transaction data to be passed to the new distributor at the time of separation. After the separation date, Customer Care can provide the data for a fee.

What happens if returns are denied?

If we are unable to match the serialized data to a product that was shipped from one of our distribution centers, a return authorization will not be issued for that product. If we receive product at our distribution centers that is not included on the return authorization and we are unable to confirm it was shipped out of one of our distribution centers, that product will be shipped back to you.

Receiving and returns

Will the returns process be changing once DSCSA goes into effect?

On November 27, 2024 and beyond when processing your return/claim, all salable product being returned must be associated with the original invoice and serialized data prior to the authorization being issued. The returns process in ABC Order will allow you to type in the serial number, use a 2D scanner, or prompts will allow you to search for the item.

Is a 2D scanner required for the returns process?

A 2D bar scanner is not required, but we recommend obtaining a 2D barcode scanner for the fastest, most efficient, and accurate option.

Is there a recommended 2D scanner to use?

There are many barcode scanning options in the marketplace. Here are the minimum product specs you should ensure your scanner has:

- Must be able to scan 2D barcodes
- High resolution megapixel sensor. This will help to capture problematic barcodes, such as ones that are poorly printed, crinkled, faded or distorted.
- The scanner can scan DataMatrix
- Scanner can be battery operated or plug into a computer

Some examples of scanners we would recommend are:

- Zebra DS8100 Series
- Zebra DS2200 Series

If the barcode and human readable information are unreadable, how are those returns handled?

You can call our customer service to workthrough the returns process.

Receiving and returns

If I choose not to scan, how else can I manage returns?

There are several options in ABC Order to identify the item you need to return. You can key in the serial #, search by item & invoice to find the serial # or call customer service for assistance.

Many times, I contact the distribution center directly if there is an issue with a shipment. Moving forward, if there is a question about serial numbers, who can best help with this?

Please contact SecureSupplyChain@amerisourcebergen.com for assistance with all DSCSA related questions, especially related to serial numbers.

Are recalls handled the same as returns?

Recalls are considered unsaleable returns, so the existing process remains the same.

Will I be able to notice if a serial number has been tampered with?

Yes. The processes that we will put in place to scan each individual product, along with the data sent by the original Manufacturer, will be able to alert us to any suspicious activity which will lead to us opening a suspect product inquiry. However, there is an exemption in DSCSA that says if that shipment of product between dispensers is for an emergency medical authorization or an emergency medical use or an immediate patient need, there is no DSCSA transaction that must occur because there is an emergency patient need.

How will the new requirements impact returns for 340B products?

All saleable returns must be associated with the original invoice and serialized data. This means that all 340B products must be returned under the 340B account who originally placed the order.

Electronic Product Code Information Services (EPCIS)

What is the purpose of an Electronic Product Code Information Services (EPCIS) file?

It is the electronic, interoperable data exchange method for serialized data.

What is required of me regarding an Electronic Product Code Information Services (EPCIS) file?

To be compliant with DSCSA, you only need to be able to access an EPCIS file when required. EPCIS files for each invoice will be available for customers through the reporting module in ABC Order. You will need an ABC Order log in to access that report. It is not required for you to print or independently store EPCIS files. We will host the file through ABC Order allowing you to access when needed.

What kind of software will be needed to implement DSCSA compliance regarding Electronic Product Code Information Services (EPCIS)?

There is no software required for DSCSA compliance. If you would like to have the EPCIS file pushed to you directly, then you will need to work with a third-party EPCIS vendor. We are using an EPCIS 1.2 document format. You also have the option of pulling their serialized data through the DSCSA Report in the ABC order platform. **Having access to the serialized data through either method makes a customer DSCSA compliant.**

What is the cost of working with an EPCIS Vendor?

We do not charge any fees to integrate with your EPCIS vendors; however, each vendor will likely have fees on their side.

Will I be required to download the EPCIS reports daily, or will Cencora store them online?

You are not required to download the reports. You just need to be able to access the data. We will store this data for 6 years.

Electronic Product Code Information Services (EPCIS)

Will pharmacy software vendors incorporate EPCIS into their software?

Each EPCIS vendor will likely have their own offering. Some might be able to integrate with your pharmacy software system. This is something to consider when asking your pharmacy management solutions if you are interested in receiving the EPCIS data from us.

How will I access the EPCIS data for drop ship orders?

We will receive the EPCIS data from the manufacturers and pass it through to the customer.

What is the workflow process for the EPCIS file once DSCSA goes into effect?

As a dispenser, you have 2 options; you can select to receive an EPCIS file from Cencora (formerly AmerisourceBergen) which will require you to have a system or solution provider in place that will be able to ingest the EPCIS data file. The other method is that we will track and maintain the list of serial numbers that you purchase on our ABC Order website and will allow you to download the files as you need them. You are **not required** to scan inbound product coming into your locations.

Can I get EPCIS data set up to have an automated report sent to me summarized at the 5K level (Not to a third-party vendor, but to me)?

In order to receive an EPCIS file, we need an AS2 connection between us and the receiving party. You will also have the option to pull the serialized data for your accounts through the DSCSA Report in ABC Order.

If I am using an EPCIS third-party vendor, how can I check their onboarding status with Cencora?

If you have chosen to work with third party solutions provider, you will need to work with them directly for any onboarding updates. Cencora is working to onboard EPCIS vendors by solution provider, not by individual accounts.

Electronic Product Code Information Services (EPCIS)

If I need the DSCSA data, will I be able to receive that through a requested electronic EDI 856 file?

An EDI 856 file is a separate transaction from what is required for DSCSA. We will continue to send EDI files after November 27, 2023, and they will continue to be DSCSA compliant until the FDA takes action to enforce the law November 2024. Once DSCSA enforcement begins, a transmission of serialized data can occur via an EPCIS (Electronic Product Code Information Service) data transmission. You will also have the ability to download your DSCSA report through the reporting module in ABC Order.

If I already receive DQSA data through an EDI 856 (Advanced Ship notification – ASN), do I need anything else?

Due to the one year stabilization period laid out by the DSCSA until November 2024, the DQSA 856 file will remain DSCSA compliant after Nov. 27, 2023. You will continue to receive the 856 transactions.

Will the GTIN (global trade item number) be added to ABC Order?

This information will be available in the **new DSCSA report** that will be available in ABC Order in. The timing on this addition is still being determined. We are still gathering requirements to support providing enhanced DSCSA reporting in ABC Order and developing a returns solution to support the returns process mandated by DSCSA. You also have the option to receive an EPCIS file for all product that is shipped to them, which contains the GTIN.

Global Location Number (GLN)

What is a GLN?

Powered by GS1 Standards, the Global Location Number (GLN) provides businesses the ability to know who is involved in transactions and where things are located throughout the supply chain. By uniquely identifying parties and locations, the GLN helps with tracking products, optimizing processes, and providing greater visibility to shipments moving through the supply chain.

Why is a GLN important?

DSCSA requires the use of international standards as defined by GS1. The GLN (Global Location Number) identifies unique locations by assigning a unique 13-digit numeric code to each location.

- We cannot send information on the product without the standardized GLN for identification.
- We cannot complete the EPCIS file (Data file that contains serialized product shipment details for DSCSA covered items and represents transfer of ownership of materials included in the shipment) for your order without it. The purchase order will be marked incomplete without a GLN on file.
- Without a GLN, you will be out of compliance with the DSCSA federal regulation and we will not be able to transact business with you.

Who is required to have a GLN?

This GLN requirement is for all customers within the supply chain, regardless of where product is purchased. Every location that receives or dispenses product from any distributor will require a GLN. This includes secondary accounts that do business with us and all customers regardless of size.

Does DSCSA apply to 340B pharmacies and if so, does the contract pharmacy need to have a GLN or the Covered Entity?

Yes, DSCSA applies to 340B pharmacies. That means if a contract pharmacy is being shipped to or is selling products, they will be required to have a GLN. All shipped to and sold to locations are required to have a GLN.

Global Location Number (GLN)

How do you obtain a GLN?

We are in the process of reviewing all GLNs that are already enumerated through GS1 and updating your accounts within our database to reflect this information by November 2024. To ensure the continuity of shipments once DSCSA goes into effect in November, AmerisourceBergen and other distributors have purchased a group license through GS1, which enables us to apply a Global Location Number (GLN) for those who do not currently have a GLN or are unsure if they have a GLN.

What do you need to do if you do not have a GLN?

If you do not have a GLN or are unsure if you have one, we are proactively working on providing one for you by November 2023. While there is no need for you to take any action at this time, it is still important to understand the purpose of a GLN.

Do you already have a GLN?

If you have your GLN information or obtain a GLN on your own, please send an email to SecureSupplyChain@amerisourcebergen.com and CC your sales rep with the following details:

- Account name
- Account number
- Account address
- GLN number
- DEA # (if available)

Will the Cencora name change impact my GLN number if purchased on my behalf?

AmerisourceBergen purchased GLN codes prior to its name change to Cencora. We will be transferring our GS1 identifier to Cencora. Your GLN number will not change because of our name change. The GS1 prefix associated with AmerisourceBergen won't change when we transfer to Cencora.

Global Location Number (GLN)

What do I do if I have a general question or update to my account?

Please email SecureSupplyChain@amerisourcebergen.com and our team will work with you to answer any questions or account updates you may have.

What do you do if you have a question or concern on updating a GLN through GS1?

If you need assistance finding your GLN or GLN account related questions, please reach out to gs1usdscsa@gs1us.org and the GS1 team will work with you to answer any questions you may have.

If an account changes ownership, is there a requirement to get a new GLN or can you transfer the GLN associated with the address to its new owner?

The account owner of the GLN in GS1's database can request that the GLN ownership be transferred to the new GLN owner. You can also email GS1 at gs1usdscsa@gs1us.org and request that the ownership be transferred.

Do any products purchased from Cencora/AmerisourceBergen require each pharmacy location to have a GLN?

DSCSA requires any physical location that can receive shipment of product to have a GLN. The GLN is a unique identifier that will allow the FDA and state agencies to run tracing requests and be able to track specific serial numbers in the U.S. supply chain.

Who is creating/maintaining GLN numbers?

GS1 enumerates all GLNs throughout the supply chain. We are reviewing all GLNs that have been enumerated through GS1 and updating accounts accordingly. For those who do not already have a GLN, we will be assigning you a GLN by November 2024. This process extends across all our customers regardless of size or class of trade.

Global Location Number (GLN)

How do customers request GLNs for locations that AB doesn't service?

We will be providing GLNs to all billed to and shipped to locations of customers we service. If you are interested in acquiring a GLN for locations serviced by other wholesalers can work directly with that wholesaler or obtain a GLN through GS1.

If I order from both wholesale and SmartSource, will I need multiple GLN numbers?

A GLN is assigned to each unique address. If you have a wholesale account and a SmartSource account listed at the same address, you will only need one GLN.

If have a WAC, GPO, and 340B account tied to the same physical location, does each account require a GLN?

Since they are all the same physical location, all three accounts will be tied to the same GLN.

Is there a charge for obtaining a GLN?

We do not charge a fee for obtaining a GLN for our customers. GS1 does charge a fee if they work to get a GLN on their own.

If you originate the GLN on my behalf and you own the GLN as the parent entity, what happens if I am no longer affiliated with Cencora?

You can request that we transfer the ownership of the GLN to another parent GLN. Is the GLN taking the place of the HIN (Health Industry Number) on my account? No, the GLN does not replace the Health Industry Number.

Global Location Number (GLN)

If a specialty practice name is on the ship to address but the base address is identical, do we need 2 separate GLNs? i.e. is 130 Cedar Rd the same as 130 Cedar Rd Urology?

The practice name shouldn't drive anything. If the ship to address is the same, it should be assigned a single GLN.

Will you be able to track all of my purchases even from other vendors if my GLN was provided by you?

We will only have record of the shipments that come from our distribution centers no matter who "owns" a GLN. However, if you prefer to enumerate your own GLN, be sure to provide us with that GLN so we can ensure it is on file with your account.

Are we assigning GLNS to all accounts, even those that use as a secondary wholesaler?

The first phase of the GLN process is to identify if there is an existing GLN already assigned to your physical location in the GS1 DataHub. This applies to both primary and secondary accounts. If we are unable to find an existing GLN, we will work with GS1 to get one assigned in order to be in compliance.

If I change my address, thus meaning the GLN would be different since the physical location changed, am I blocked from ordering until we populate their GLN?

If you move locations and don't get a GLN on your own for your new address, please notify us of your new address so our team can work to provide you a GLN for your new location. If we assist you in obtaining a new GLN for a new address, we will inactivate the old one and update our records. We will ensure you are not blocked from ordering and there is no disruption to the supply chain while the new address GLN is being enumerated.

Global Location Number (GLN)

What do you do if you have a general question or update my Cencora account?

Please email SecureSupplyChain@amerisourcebergen.com and our team will work with you to answer any questions or account updates you may have.

How will GLN maintenance be managed if I change locations or add a practice?

Regardless if you obtained your own GLN or we enumerated one on your behalf, the address tied to that GLN can be updated through the GS1 database. The GLN will be able to follow you or your new practice wherever you go.

If a practice changes ownership but address remains the same, can the same GLN number be used?

If the ship to address is the same, it should be assigned a single GLN.

If I am a new customer, how will GLNs be handled?

In the current state, before DSCSA goes into effect, there is a GLN field within our workspace onboarding guide. If you already have a GLN and knows what it is, you can enter it in the workspace workflow. If you don't have one or don't know you have one, we will enumerate a GLN on your behalf.

After DSCSA goes into effect on November 27, 2024, if you move to us from an existing wholesaler, you should already have a GLN assigned per DSCSA requirements. If you do not have a GLN or do not know what it is, we can search the GS1 database to assist you. If you are a brand-new customer, we will work with you to get a GLN assigned to your location(s).

How is the industry handling duplicate GLNs?

Led by GS1, an industry-wide GLN cleanup is underway to reconcile and remove duplicate GLNs that were created throughout the industry in error over the last year. Cencora is actively involved in the cleanup and are adjusting the GLNs within our master data as needed. As we work through this cleanup process, any changes to your GLN will be reflected in ABC Order.

Small dispenser exemption and waivers, exceptions, exemptions (WEE)

What is the Small Dispenser Exemption under the DSCSA?

The Small Dispenser Exemption allows dispensers with 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians, as of November 27, 2024, to be exempt from certain DSCSA requirements until November 27, 2026. This provides small dispensers additional time to stabilize their operations and fully implement the enhanced drug distribution security requirements.

How do I know if my pharmacy qualifies as a small dispenser?

Your pharmacy qualifies if, as of November 27, 2024, the company that owns the dispenser has 25 or fewer full-time employees who are licensed pharmacists or qualified pharmacy technicians. Who could be considered a small dispenser: Independent pharmacies Physician and community practices

What does the Small Dispenser Exemption mean for my pharmacy's operations?

Small dispensers have additional time to establish Standard Operating Procedures (SOPs) and processes for DSCSA compliance. However, the new returns process will still apply starting this November, requiring dispensers to track serial numbers for every return to remain compliant.

What are WEEs under the DSCSA?

WEEs refer to Waivers, Exceptions, and Exemptions that authorized trading partners can request if they are unable to meet certain enhanced drug distribution security requirements of the DSCSA by November 27, 2024. You can learn more [here](#).

When can a waiver be requested?

A waiver can be requested if complying with the DSCSA requirements would result in undue economic hardship or for emergency medical reasons, including public health emergencies.

Small dispenser exemption and waivers, exceptions, exemptions (WEE)

What is an exception, and when can it be requested?

An exception can be requested if a product is packaged in a container too small to accommodate the necessary labeling for compliance with section 582 of the FD&C Act.

What is an exemption, and when can it be requested?

An exemption can be requested for other products or transactions to maintain public health or for other appropriate reasons. This helps ensure continued access to necessary medications even if they cannot fully meet DSCSA requirements.

How do I apply for a WEE?

You can apply for a WEE by submitting a request through the FDA [here](#).

What should I do if I have concerns about readiness or patient access but do not qualify for the Small Dispenser Exemption?

If you do not qualify for the Small Dispenser Exemption and have concerns about readiness or patient access, you can request a WEE to address these issues.