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Serial Number Decommissioning Pilot Report

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Executive Summary

The Drug Supply Chain Security Act (DSCSA) requires the serialization of products down to the saleable unit. Serialization enables the electronic and interoperable exchange of data between trading partners, as well as other communication tools like product verification and product tracing that should help prevent counterfeit medications from infiltrating the legitimate prescription drug supply chain. While full implementation of DSCSA has been delayed to ensure that patients do not experience access issues to medications, even when fully implemented, the law has some limitations that have and will continue to be exploited. Counterfeit prescription products continue to infiltrate the legitimate supply chain. Recent counterfeit events have highlighted numerous instances where valid unique product identifiers – Global Trade Item Numbers (GTINs), or serial numbers – were duplicated or reused by bad actors to insert dangerous products into the legitimate supply chain. Further collaborative efforts are required to prevent these dangerous products from entering the supply chain.

In response, the National Association of Boards of Pharmacy® (NABP®) organized a focused, voluntary pilot that would explore the facilitation of decommissioning serial numbers as a foundational step in further preventing and detecting counterfeit medicines. The Serial Number Decommissioning Pilot explored how the industry might work together to prevent the growing tactic of counterfeiters that reuse already-dispensed prescription drug packaging with valid product identifiers. Key stakeholders from the manufacturing and dispensing communities joined the effort to see how the building blocks of DSCSA (product identifiers and 2D bar code scanning) could be leveraged to further protect the legitimate supply chain from counterfeits. The pilot design mostly revolved around the following core questions:

1. Is it possible, in any or all situations, to capture end-of-commerce event information for serial numbers that have been dispensed, damaged, destroyed, stolen, or other and translate those events into a serial number being “decommissioned”?
2. Can these events be captured in various product quantity configurations in the current “unit of sale” without a move to full “unit of dispense” for all products?
3. Could capturing and sharing with the manufacturer/repackager of such decommissioning events have helped in preventing recent types of counterfeiting events?

During the pilot, participants identified several guiding factors that should be considered as the industry weighs how to address the proliferation of counterfeit medications into the legitimate supply chain. The following guiding factors were developed before, during, and because of the pilot:

1. Only a portion of product is currently packaged and serialized at the “unit of dispense” level, but this portion includes a majority portion of recent counterfeit cases involving single-packaged vials, smaller-count pill bottles, and, more recently, auto-injection pens.
2. DSCSA provides tools that should be leveraged as foundational in preventing counterfeits, such as saleable carton serialization, data-sharing techniques, product verification, product tracing, related global standards, and the development of industry best practices.
3. DSCSA has limitations in that product verification can be performed at any time but is only required after a suspect product is identified.
4. DSCSA requires that trading partners use widely aligned DSCSA tools, such as Electronic Product Code Information Services (EPCIS) messaging, product verification, and product tracking.
5. DSCSA requires that regulators, manufacturers/repackagers, and direct trading partners are efficiently notified of illegitimate product identifiers.
6. The technology and regulatory frameworks exist to scan products (or integrate them into existing scan systems) in order to verify product identifiers and decommission serial numbers at or near the point of dispense.
7. Adoption of any methods beyond clearly mandated requirements such as end-of-commerce scans will require nonregulatory incentives.
8. The variability of products, processes, and conditions present in the market requires that any solution focus on early adopters in narrow, high-counterfeit target areas, such as high-value products or other historically counterfeited product types.

9. Dispensers need a flexible approach that allows the capture of events at the most efficient points, along with options to integrate into existing workflows and systems.

At the conclusion of the pilot and based on findings outlined below, the pilot team believes that:

1. Industry should move forward in search of pathways to enable the capturing and sharing of decommissioning data while expanding the ability to verify product identifiers;
2. These efforts could have prevented or significantly limited the historical counterfeit events that involved the reuse of valid product identifiers by providing immediate visibility to unfolding threats;
3. Early efforts should focus on products most susceptible to counterfeiting; and
4. NABP should expand its work and collaboration across the supply chain to further protect patients and prevent harmful products from entering the legitimate supply chain.

Introduction

Enacted in 2013, DSCSA established requirements for members of the United States prescription drug supply chain intended to protect the legitimate supply chain from counterfeit/falsified medicines. The requirements established that manufacturers should serialize products by affixing a unique product identifier to the lowest saleable unit of the product. The serialization would also include a global standards 1 (GS1) 2D data matrix that can be scanned throughout the product's "movement" in the supply chain. DSCSA also affords trading partners and regulators tools to identify suspect and illegitimate products by scanning the 2D data matrix to determine the authenticity of the product identifiers (product verification) and to trace the prior ownership of the product (product tracing).

Recent cases of illegitimate medicine being found in the legitimate US supply chain continue to highlight the need for increased efforts to further secure the US supply chain. While the US supply chain remains among the safest in the world, these cases emphasize how organized crime and counterfeit operations have evolved beyond the protections enabled by DSCSA (including the unique GTIN, serial number, and related 2D data matrix barcode). In these recent counterfeit cases, it has been shown that bad actors often leverage actual, existing serial numbers by reusing packaging or copying existing barcodes. In industry-wide updates with the manufacturers of the related brands, it became clear that serial number "end of commerce" capture should be explored as a preventative approach to these threats.

The Serial Number Decommissioning Pilot was performed by NABP in collaboration with participating prescription drug manufacturers and dispensers from April through May 2024. Built upon the product-tracing capabilities of Pulse by NABP™, the pilot set out to demonstrate the viability of a process that would fill a gap in medication supply chain safety, namely, to ensure that serialized products, once dispensed, cannot be reintroduced into the supply chain, thus protecting patients from receiving counterfeit medications manufactured in original packaging.

Background

In early 2000, a series of high-profile counterfeit cases including drugs that treat cancer, renal failure, high cholesterol, and AIDS were documented through news, press releases, and investigative journalism, highlighting weaknesses in the US prescription drug supply chain. These and other historic events led to the passing of DSCSA in 2011 to facilitate the tracking of ownership changes of any applicable saleable unit to help identify the supply chain and source of detected counterfeits.

In late 2020, Janssen Pharmaceuticals (Johnson & Johnson) announced that they had been made aware that counterfeit Symtuza®, an HIV treatment medication, had been received by three pharmacies in the US. Janssen later took legal action to ensure the alleged distributor no longer introduced counterfeit products into the legitimate supply chain.

In 2021, Gilead Sciences, Inc, became the first pharmaceutical company to take direct legal action against counterfeiters manufacturing HIV counterfeits using already-dispensed original bottles. It filed its lawsuit knowing only a handful of patients received counterfeit versions of its HIV medicine but later identified through seized records from the counterfeiters that they had sold over $250 million worth of illegitimate HIV drugs into the legitimate US supply chain. The medications made their way to over 600 unique pharmacies across 36 states. In summary, findings from law enforcement show that what was most valuable to the criminals was not the medication in the bottle, but the bottle and packaging itself. While recent laws and guidance documents have helped to shape a foundation for the serialization of prescription drugs, they focus on the ability to trace the supply chain for a product after it has been identified as suspect or illegitimate and do not involve capturing the critical information of when products are removed from the supply chain (ie, product that has been dispensed and subsequently decommissioned).

Under DSCSA, prescription medicines must be serialized down to the saleable unit. In addition, product packaging must contain human-readable product identifiers that are also encoded in a 2D data matrix barcode.

To bypass the DSCSA systems, criminals obtained products in the manufacturer's original packaging and then duplicated these active product identifiers or simply cleaned the bottles, removing any identifying patient or pharmacy information to make the bottles look new. Because the packaging also contained the valid product identifiers with a serial number and 2D barcode, if a pharmacy or wholesale distributor attempts to conduct a "product verification"[1] with the manufacturer to confirm that the product identifiers on these counterfeits are genuine, the manufacturer would almost certainly confirm verification because the manufacturer would have no information that the bottle bearing those product identifiers was already dispensed.

The reason this is possible in the US is that DSCSA does not require serial numbers to be decommissioned or have related status updates when a product is dispensed. In the US, unlike the European Union's (EU's) Falsified Medicine Directive, the serialized product is **not** always packaged in a "unit of dispense" and is not required to be linked to a patient dispensing event. While the intent was to avoid creating a cumbersome dispensing event for all medicine, the impact here is that the information that a product is dispensed or otherwise decommissioned is not captured to be shared. Therefore, legitimate serialization unique identifiers can be reintroduced into the supply chain without clear detection of being duplicates. In addition, any product that is returned to a distributor or manufacturer for destruction is outside of DSCSA requirements due to the product's classification as exempt from further transaction under the non-saleable returned inventory provisions of the law and is never decommissioned. This means that if an already-dispensed product is reintroduced intentionally or accidentally, the manufacturer may also provide an affirmative response to any verification that the product identifiers are still legitimate. Both situations have been exploited in the highlighted cases, as well as in other counterfeit events, and even completely compliant implementations of DSCSA requirements will not prevent such recurrence.

Pilot Objective

While DSCSA does not require the capturing of these decommissioning events, thought leaders from across the supply chain have suggested that a proof-of-concept pilot event could help the industry learn the benefits, challenges, and viability of dispensers capturing the dispensing and other end-of-commerce events and relay such transactions to the manufacturer or repackager of record.

The objective of the Serial Number Decommissioning Pilot was to explore the initial business processes and systems for alerting or preventing serialized product from being dispensed more than one time, thus protecting patients and providing information to manufacturers to decommission the serial number or otherwise allowing them to initiate a suspect product investigation.

It was clear that a significant challenge in the proof of concept was helping to understand if such activity could take place without full conversion of product to "unit of dispense," as is the case in the EU and many regions of the world. This requires engaging leading manufacturers whose product was counterfeited in these highlighted cases and working with dispensers of various practice settings and sizes.

Pilot Approach

Building off NABP's previous DSCSA pilot projects that demonstrated the product-tracing capabilities of Pulse by NABP, NABP explored the following decommissioning use case to attempt to answer the questions above. The pilot was intended to leverage the following capabilities of Pulse:

- Provide a neutral platform for any stakeholder to leverage industry-wide functions.
- Leverage the Trading Partner Directory feature of Pulse to allow connection and collaboration with any other trading partner.
- Draw from past work done on product-tracing exploration to further explore in an agile manner.
- Build on a flexible framework that facilitates direct user interactions or application programming

[1] Verifying the product identifiers (GTIN, lot number, expiration date, and serial number) with the manufacturer of the product.

interfaces (APIs) for any authorized system to integrate.
- Continue to utilize existing GS1 industry standards while flagging areas where gaps may exist for follow-up with GS1.
- Allow NABP to serve its mission as an independent agent in evolving patient safety.

Use Case: Notification of Dispensing Events

In this use case, pharmacies used the Pulse platform to scan a 2D barcode of a prescription drug product that was at or near the point of dispense. The scan generated an event in the prototyped version of Pulse, and the related data was stored to show any scan performed. Manufacturers were given access to a query report that allowed the viewing of these events with data limited to the date, time, GTIN, serial number, lot number, and expiration date. Additionally, manufacturers could be sent a download of the data conclusion of the pilot to further analyze and explore.

Participants included state-licensed pharmacies and pharmacists, manufacturers, and the NABP pilot team. The following pharmacies participated in the pilot:

- Sam's Health Mart Pharmacy #1, #2, and #3 in Missouri
- Gateway Apothecary, Inc, in Missouri
- Indiana University Health

Each participating pharmacy carried products manufactured by Gilead Sciences; Genentech, Inc; and/or Johnson & Johnson.

Each participant organization assigned a user who was responsible for logging into Pulse to perform their role. Participation took place virtually, with product barcodes being scanned behind the counter in a state-licensed pharmacy.

Materials for this use case included a mobile device and prescription drug products selected by the participating manufacturers that had 2D barcodes, product identifiers consistent with DSCSA, and that were ready for decommissioning (eg, an empty bottle ready for destruction or a bottle that had been dispensed intact). The technology in use was Pulse via mobile web interface and desktop web interface. No technical development, integration, or interface was required for this pilot.

The process flow was as follows:

1. A state-licensed pharmacist (user) logged into Pulse on their mobile device.
2. User selected "Decommission SN" (serial number).
3. User scanned 2D data matrix on the product.
4. Pulse displayed the following information:
    a. GTIN
    b. Serial Number
    c. Lot Number
    d. Expiration Date
5. User confirmed that the scan result matched the product identifiers and submitted.
6. The decommissioning event was received in Pulse.
7. Date and timestamp of event were recorded in Pulse.
8. The manufacturer logged into Pulse to view message.
9. Message displayed the following data elements:
    a. GTIN
    b. Serial Number
    c. Lot Number
    d. Expiration Date
    e. Date/Time the event was initiated

The pilot adhered to the following tenets:

1. No technological development, integration, or interface were required by the participants.

2. Serial numbers were not associated with any patient, patient's agent, other personally identifiable information, or personal health information.
3. Serial numbers were not disclosed to any party outside of the pilot.
4. Serial number information was purged and electronically destroyed at the end of the pilot.
5. The pilot did not disclose any event location data to manufacturers.
6. Above all, the pilot was focused on advancing patient safety by reducing the likelihood or increasing the detection capability of illegitimate products.

Pilot Results and Discussion

Scanning Statistics: The total number of 2D barcode scans, the number of unique serial numbers recorded, and the success rate were collected. During a two-week period in late April 2024, a total of 282 scans were performed, and 261 unique serial numbers were scanned, resulting in a 92.55% success rate.

Duplicate Scans and Records: Data received from two participating manufacturers contained duplicate records that were the result of users either inadvertently scanning the same package twice or clicking "send" twice. Suggestions for reducing accidental duplicate scans included auditory cues indicating when a scan has successfully registered a serial number in the system or system techniques to reduce inadvertent duplicates.

These duplicates pointed to a need to distinguish between records that are erroneously duplicated and products that are potentially counterfeit. Participants noted that if the duplication occurs within a certain timeframe, it can be discounted, but if it occurs at multiple time points, it will indicate a potential problem. The question was raised whether the system would alert users that a serial number has already been decommissioned. One suggestion was to add the capability to sort records by timestamp proximity. It was also highlighted that there may be occasions of duplicate scans that simply show that a product was accidentally scanned twice or was a controlled return that may be determined as normal and not suspicious product.

Factors Affecting Scanning: Some participants had trouble scanning 2D barcodes, either because the barcodes were small or blurred or because the scanners being used (eg, cellphone cameras) were not sufficiently high-resolution. Dispensers noted that larger barcodes could be scanned without a problem. The size of the barcode, however, varies with the size of the package. The pilot dispenser participants noted that there may be an opportunity to integrate with pharmacy scanners, which would increase the volume and accuracy of scans and help to scale the pilot more broadly.

When to Decommission: Questions arose about the process, such as the circumstances in which to decommission a product. Participants agreed that a package that has been opened should not be dispensed, but questions remained as to other use cases, such as when product is a salable return or sent for destruction and whether that would warrant a second decommissioning. Some dispensers indicated that they would prefer to scan the serial number at the time of receipt, internal distribution, or shelf/cabinet stocking.

Pharmacies scanned products that were dispensed in the manufacturer's original packaging, as well as products for prescriptions that were filled out of a larger stock bottle and placed into a smaller vial. Manufacturers with large stock bottles indicated that they preferred that products be scanned at the point that the stock bottle is opened. Their thinking is that, at that point, the product should not be dispensed from another location or otherwise processed as a saleable return.

User Interface: Manufacturers indicated that additional data fields and functionality would be useful. This includes further functionality to visually or systemically distinguish between new records and those that have been read or forwarded. Additional fields that manufacturers had asked about and will need more industry alignment to include consist of the product name, pharmacy that scanned the product, time zone when the record was entered, and the type of event (if scanning is done at earlier points of the handling processes). Also, it was mentioned that capturing who is performing a scan (potentially connecting with Pulse by NABP profiles) and in what geographical location the scan was performed would help to distinguish between inadvertent duplicate scans and potential nefarious activity that requires further analysis.

Reporting/Exporting Data: Manufacturers asked for flexibility in how the captured information is obtained. Some wanted the ability to download or export data into a spreadsheet to share with others in their organization, while many suggested integrations would be needed to send the events either in batch or real-time transmission. Additional functionality might include standard reports for monitoring activity, such as duplicate serial numbers, a new dispenser source, or serial numbers in a inactive state.

Workflow: Different workflows in pharmacies presented other potential use cases. Central fill, for instance, may involve the automated scanning of products being distributed to pharmacies. The timing of when product scanning occurs (eg, in batches) may also vary by pharmacy.

While scanning to dispense/decommission as soon as possible after opening the serialized bottle/box is preferred, there is a need to address situations in which this scan can only happen at different points in the workflow. For example, some pharmacies may remove the serialized box when stocking product into a dispensing cabinet, some may only consider scanning serialized barcodes at the point of receipt to the pharmacy dock or central fill location, or there may be automated scanning at central fill only. This issue will require further exploration with system providers and dispenser stakeholders to understand and determine if there is a need to systemically identify at what point in the workflow and in what location this scan is occurring.

EPCIS Structure: Manufacturers expressed a desire to move toward a GS1 standard – namely, an EPCIS structure – to help facilitate the interoperability of data among trading partners. It was noted that the GS1 1.3 US implementation guide includes scenarios for events including dispense, partial dispense, and decommission. The pilot team indicated that, while the information collected through the pilot project establishes a firm foundation for potential future standardization, the pilot intends to determine whether the platform helps to prevent prescription drug counterfeiting. If this is established, it may lead to informing a process for standardization. Others noted that the existing product VRS (verification routing service) may be leveraged for its Lightweight Messaging Standard format that could include a “dispense” reason code.

Demonstration: NABP staff demonstrated the pilot’s functionality while participating in the Drug Enforcement Administration (DEA) Diversion Control Division’s Supply Chain Conference in late April. DEA agents at the conference reported the diversion of promethazine, which is sometimes sold illegally and used recreationally. Staff was able to scan the 2D bar code on a case of stolen product and immediately determine the appropriate person with the appropriate manufacturer to initiate an investigation, thus demonstrating a valuable use case for the Pulse platform and its decommissioning capabilities.

Future Developments: Unless dispensers, and, in particular, small independent pharmacies widely utilize product verification, DSCSA may never reach its full potential. While DSCSA requires pharmacies to verify a product if it is considered to be suspect, participants noted that a gap still exists. The group agreed that an effective serial number decommissioning process would require verification of every product dispensed. Pilot participants discussed future developments that would be needed to expand the Serial Number Decommissioning Pilot process on an industry-wide scale. Toward this end, participants expressed the importance of providing pharmacies with access to product verification tools, as this will facilitate the development of pharmacy best practices that include scanning products at the point of dispensing and verifying products with manufacturers prior to dispensing. They noted that payers could play a role in normalizing product verification at the point of dispensing by requiring pharmacies to submit the serial numbers of products dispensed.

The group recognized that statutory and regulatory changes to require verification and/or scanning at the point of dispensing are highly unlikely. Accordingly, without a regulatory mandate, other factors would be needed to incentivize pharmacies to scan products at the point of dispensing. Participants agreed that dispensers would need to see a return on investment beyond patient safety. It was noted that revenue, such as compensation for the service of scanning and the resulting data product, may be an effective driver. Participants noted that some manufacturers have direct dispensers, in which case the manufacturers could require the dispensers to comply with the process through their contracts. Gaining compliance from the multitude of indirect dispensers, however, would be much more challenging. Participants also considered whether scanning at the dispenser level could be tied to incentive methods such as manufacturer rebates to help offset costs incurred at the dispenser and

drive adoption.

It was suggested that the group consider the commercialization and commoditization of data as a path forward. Manufacturers can assign a value to granular and timely data and determine the value of a serial number scan at the point of dispensing. This value may vary across products.

Recommendations

After several weeks of testing, discussion, and deliberation, the pilot team made the following recommendations for improvements to the Pulse serial number decommissioning system and process:

1. Share pilot findings with additional members of the prescription drug supply chain, including distributors, chain pharmacies, and other stakeholders, to collect further feedback for consideration in follow-on efforts.
2. Continue to expand follow-on pilot trials with a broader range of dispensers to further identify variability in other environments, such as large retail, mail order, institutional and governmental, and other environments.
3. Explore integrating pharmacy information systems with the Pulse platform to enable pharmacy scanners to be used for 2D barcode scanning at the point of dispensing.
4. Work with industry to advance the creation of a neutral and business confidential network that will include methods to incentivize dispensers' voluntary participation.
5. Clarify methods for identifying dispensers (either anonymized, permission-based named, cryptographically linked, or other).
6. Improve API integration with manufacturer systems to make the information easily available and accessible.
7. Implement auditory cues indicating when a scan has successfully registered a serial number in the system to reduce the likelihood of accidental duplicate scans.
8. Add the capability to sort records by timestamp.
9. Add the following data elements: product name, the pharmacy that scanned the product, the time zone when the record was entered, the type of event, who performed the scan, and in what geographical location the scan was performed.
10. Add functionality to create reports and export data to begin monitoring, or enable trading partners to share information with others in their organization.
11. Confer with system providers and dispenser stakeholders to determine whether there is a need to systemically identify at what point in the workflow and in what location the barcode scan should occur.

Pilot Outcomes

The pilot demonstrated that it is possible to capture product identifier (including serial number) information at the point of dispense and relay this information to the manufacturer of record, thereby allowing the manufacturer to decommission the serial number. Based on historical and recent high-profile counterfeit cases, it is believed this is one step in potentially reducing or preventing counterfeit product from being dispensed through the following ways:

- Manufacturers could monitor for duplicate or suspicious serial scanning information to more quickly identify suspicious product.
- Dispensing or other end-of-commerce events of serial numbers could be shared and updated in verification and other systems to improve the ability to give a warning if the same serial numbers are re-scanned.
- Distributors could begin to see if any product identifiers that are processed through returns show records of being dispensed to avoid excess credit.
- Dispensers could increase assurance that any dispensed and matching product is legitimate.

- Dispensers need a flexible approach that allows the capture of events at the most efficient points, along with options to integrate into existing workflows and systems.
- Enablement of this approach should include incentives to encourage adoption and offset resources required by dispensers.

The pilot team's primary observation was that the decommissioning process has the potential to warn or alert of a potentially suspect product. The goal of the process is to prevent a suspect serial number from being dispensed to a patient. If all members of the supply chain are verifying products, then dispensed serial numbers can be successfully decommissioned, and product verification could stop or significantly limit suspect serial numbers from being dispensed.

Summary

DSCSA provides foundational tools (serialization, product verification, and product tracing) that prevent counterfeit medications from entering the supply chain. The law, however, has limitations in that verification is not widely required and serial numbers are not required to be decommissioned. DSCSA will only work if the tools it provides are widely used, and if the industry continues to evolve to stay ahead of bad actors. At present, barriers exist for widespread adoption by the pharmacy community – in particular, the independent pharmacy community, which is most susceptible to counterfeiters and criminals.

To remove barriers to participation, NABP is providing all dispensers with access to DSCSA tools at no cost (eg, product verification and product tracing) and could facilitate decommission scanning with continued collaboration from industry leaders. Nonregulatory incentives must be explored to increase the utilization of product verification and to facilitate the sharing of decommissioning events at the point of dispensing.

Building on the pilot, NABP will continue to work with industry stakeholders to explore nonregulatory pathways that enhance patient safety and protect the prescription drug supply chain.