

Guidance for Avoiding Fraud, Waste, and Abuse: A Presentation for New Jersey Pharmacy Providers  
 Questions and Answers / February 28, 2024

Number	Question	Response	Responder
1	Any chance you'd consider allowing a bulk eligibility search on the NJMMIS site? It would be very helpful for us to avoid lapses in patient care. Thank you.	There are Division of Medical Assistance and Health Services (DMAHS) approved vendors on this list that provide bulk eligibility services. Go to the NJMMIS.com website and then choose Approved vendor list under the information section on the right.	DMAHS
2	Where can I find updated BIN and PCN and group name for each of the Managed Care Organizations?	<u>Fee For Service</u> BIN: 610515; PCN: SUPP NJ; GROUP: there is no Group	DMAHS (Fee For Service)
		<u>Aetna Better Health of New Jersey</u> BIN: 10591; PCN: ADV; GROUP: RX8829	Aetna Better Health of New Jersey
		<u>Fidelis Care</u> BIN: 003858 PCN: MA GROUP: 2GDA	Fidelis Care
		<u>Horizon NJ Health</u> BIN: 610606 PCN: HMC GROUP: HORIZON	Horizon NJ Health
		<u>UnitedHealthcare Community Plan</u> BIN: 610494 PCN: 4343 GROUP: AMNJ	UnitedHealthcare Community Plan
3	Is there a fee to use the NJMMIS portal?	No, there is no fee to use the NJMMIS portal.	DMAHS
4	Ownership changes only 5 years of RX records but we keep for 7?	Most pharmacy records are retained for at least 5 years (prescription and patient records, employee records, temperature records, etc). However immunization and collaborative practice related records are to be maintained for 7 years.	NJ Board of Pharmacy

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5	<p>The presentation stated that we would be required to store lot numbers of medications coming into and going out of our pharmacy. How would we be able to do that if we aren't receiving any of that information in a downloadable format?</p>	<p>Track and trace software is mandated by the Drug Supply Chain Security Act (DSCSA). As of November 27, 2023, DSCSA began requiring trading partners (manufacturers, repackagers, wholesalers, and dispensers) to provide, receive and maintain documentation about products and ownership only electronically – rather than either electronically or on paper. However, a one-year stabilization period was enacted to accommodate troubleshooting and maturation of electronic systems. While the stabilization period will last until November 27, 2024, after which trading partners will be required to provide product and ownership documentation strictly by electronic format (this requirement will not be placed on any product – or its ownership information – that is introduced into the stream of commerce before the end of the stabilization date until its expiry). This one-year period of time was not intended to be used to delay the implementation of electronic monitoring systems.</p> <p>As of June 12, 2024, the FDA has extended the implementation period until November 27, 2026 for small dispensaries (those with 25 or less full-time employees licensed as pharmacists or qualified as pharmacy technicians), if a waiver is requested and granted. Trading partners that do not qualify for the small dispenser exemptions and are unable to meet the enhanced drug distribution security requirements of section 582 of the FD&amp;C Act by November 27, 2024, may request a waiver or exemption from those requirements.</p> <p>If a transfer pertains to a transfer of a medication for a specific patient from another pharmacy, DSCSA requirements are not mandated, but the pharmacy that transferred the medication would have all of the track and trace information. 21 USCS § 360eee-1(d)(1)(A)(ii).</p> <p>If a transfer pertains to inventory received by the pharmacy from a wholesaler, they would need to work with their software vendors to ensure that they are compliant with the DSCSA regulations. All wholesalers already store this information.</p>	<p><a href="#">Information cited from FDA source</a></p>

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6	Distributors only store sales information for 6 years; doesn't the responsibility of record storage also fall on them?	<p>Per DSCSA a wholesale distributor shall capture the transaction information (including lot level information) consistent with the requirements of this section, transaction history, and transaction statement for each and maintain such information, history, and statement for not less than 6 years after the date of the transaction. 21 USCS § 360eee-1 (c)(1)(A)(v)(I)</p> <p>Per DSCSA, a dispenser (pharmacy) shall capture transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction. 21 USCS § 360eee-1 (d)(1)(A)(iii)</p> <p>Both are responsible to maintain track and trace information for 6 years.</p>	<p><a href="#">Information cited from FDA source</a></p>
7	What is the policy on using highly reimbursable National Drug Codes (NDCs) where the profit is extremely large? There are wholesalers marketing to pharmacies for this. The average wholesale price (AWP) is normally high and the reimbursement is high as well. Is there guidance on the consequences of excessive billing for these NDCs?	<p>The state and the Medicaid Managed Care Organizations that pay pharmacy claims seek to prevent payments for high cost/low value medications. To that end, there is MCO Contract language (Section 4.2.4.H) as well as a number of internal systems that MFD, DMAHS, and MCOs use to identify and prevent payment of claims for these products.</p> <p>If you are aware of a provider who prescribes such products or a pharmacy that dispenses them, please contact any of the following parties to share this information:</p> <ul style="list-style-type: none"> <li>• Aetna Better Health of New Jersey - (855) 282-8272</li> <li>• Fidelis Care - (866) 685-8664</li> <li>• Horizon NJ Health - (855) 372-8320</li> <li>• UnitedHealthcare Community Plan - (844) 359-7736</li> <li>• Wellpoint - (866) 847-8247</li> <li>• NJ Office of the State Comptroller, Medicaid Fraud Division - (888) 937-2835</li> </ul>	NJ Medicaid MCOs and MFD
8	All biologic injectable /non-injectable meds are excluded from the Drug Supply Chain Security Act (DSCSA)?	This Food and Drug Administration (FDA) webpage provides information on this topic: <a href="#">Drug Supply Chain Security Act Product Tracing Requirements   Frequently Asked Questions   FDA</a>	NJ Board of Pharmacy
9	Are home infusion providers or specialty pharmacy providers allowed to leave a delivery outside a patient's home if they have requested that? There wouldn't be anyone available to sign for it.	A signature is required for Medicaid members.	NJ Medicaid MCOs

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10	Will bulk ingredients be allowed for hazardous compounding and will NJ FamilyCare set a base for reimbursement for pediatric hazardous compounding?	See njmmis.com Newsletter Volume 23 Number 13; Active Pharmaceutical Ingredients (APIs) are excluded from coverage by NJ Medicaid (we allow APIs in compounds, but exclude from payment).	DMAHS
11	What about a change in ownership, where the Pharmacist-InCharge (PIC) remains the same. Is closing and opening control inventory still needed?	<a href="#">Please refer to N.J.A.C.13:39-4.5(a)(1)</a> as this addresses this question.	NJ Board of Pharmacy
12	Who makes decision how much to reimburse pharmacy?	Each MCO has their own network contracts. A pharmacy's reimbursement from a plan is set contractually in their agreement to participate with that plan.	DMAHS
13	Which department oversees patient lock in/restriction program and contacts?	Each MCO oversees their lock-in program, with guidance coming from DMAHS.	DMAHS and NJ Medicaid MCOs
14	Regarding 340b eligibility: 1. In reading the guidelines it appears that the payors excluded from 340b are FFS (Fee for service) Medicaid payors, and so would not include the 5 MCOs in New Jersey. Is that accurate? 2. Are New Jersey PAAD, Senior Gold, & ADDP considered to be FFS (Fee for service) Medicaid payors?	Only pharmacies operated by covered entities using 340B inventory are eligible to receive FFS payments for covered outpatient drugs when dispensed to a 340B-eligible beneficiary.  A 340B-eligible beneficiary is defined as an individual who receives medical care, typically in an outpatient setting, from the covered entity. Contract pharmacies shall not be eligible to receive New Jersey FamilyCare FFS payments for 340B prescriptions dispensed to 340B-eligible beneficiaries. Only beneficiaries enrolled under Medicare part D long with PAAD/SG and ADDP beneficiaries are considered eligible to receive FFS payment for 340B prescriptions if dispensed and billed by covered entity pharmacy.	DMAHS
15	How far in advance will we be notified for formulary changes? Insurance determines notification or state regulations for formulary changes?	Each plan has their updates on their website. Members and Prescribers are notified prior to change depending on the type of update.	NJ Medicaid MCOs