GUIDANCE FOR AVOIDING FRAUD, WASTE, AND ABUSE:

A PRESENTATION FOR NEW JERSEY PHARMACY PROVIDERS

STATE OF NEW JERSEY
OFFICE OF THE STATE COMPTROLLER

February 28, 2024

Welcome to the presentation. We will begin momentarily.

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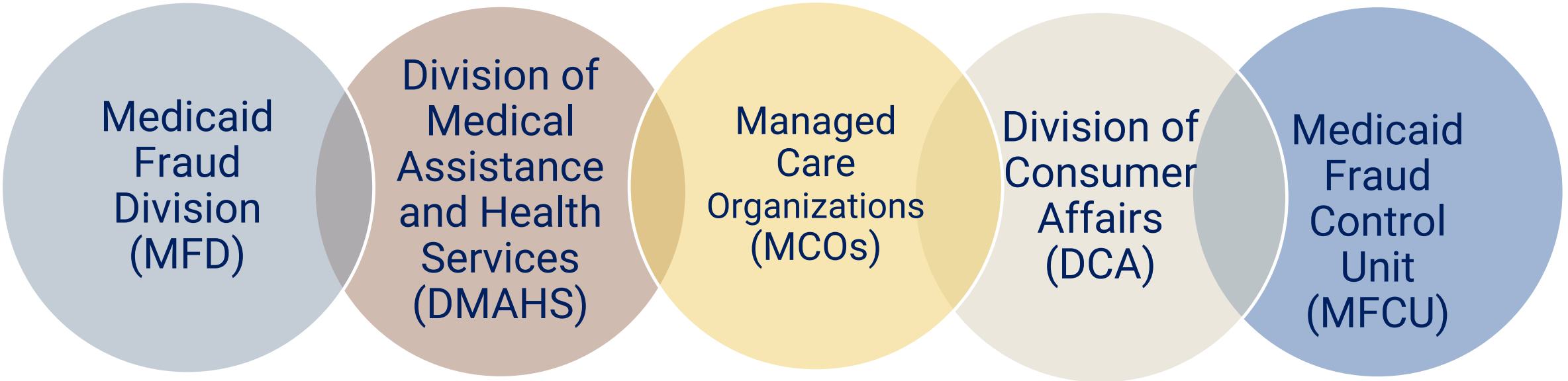
PRESENTED IN PARTNERSHIP BY:



BEFORE WE BEGIN…

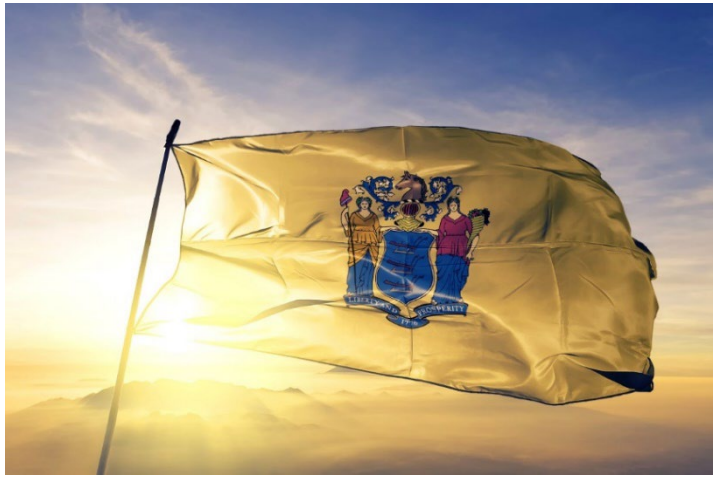
THANK YOU

for participating in the

NJ FamilyCare program!

DISCLAIMER

- This presentation is intended for general educational purposes only.
- It does not replace your responsibility to seek professional guidance, observe all laws and regulations that pertain to your practice as a Medicaid provider and exercise sound, independent, professional judgment.



GOALS FOR TODAY: TO HELP YOU BETTER UNDERSTAND

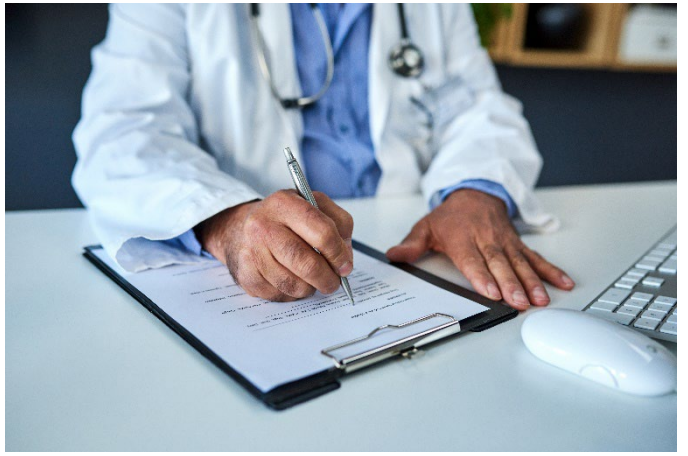
- The Medicaid program regulatory oversight structure and compliance requirements
- Potential red flag areas
- Fraud, waste, and abuse obligations of providers (prevention and reporting)
- The consequences for non-compliance by providers

QUESTIONS?

If you have questions throughout the presentation please put them in the Q & A.

WHAT IS MEDICAID?

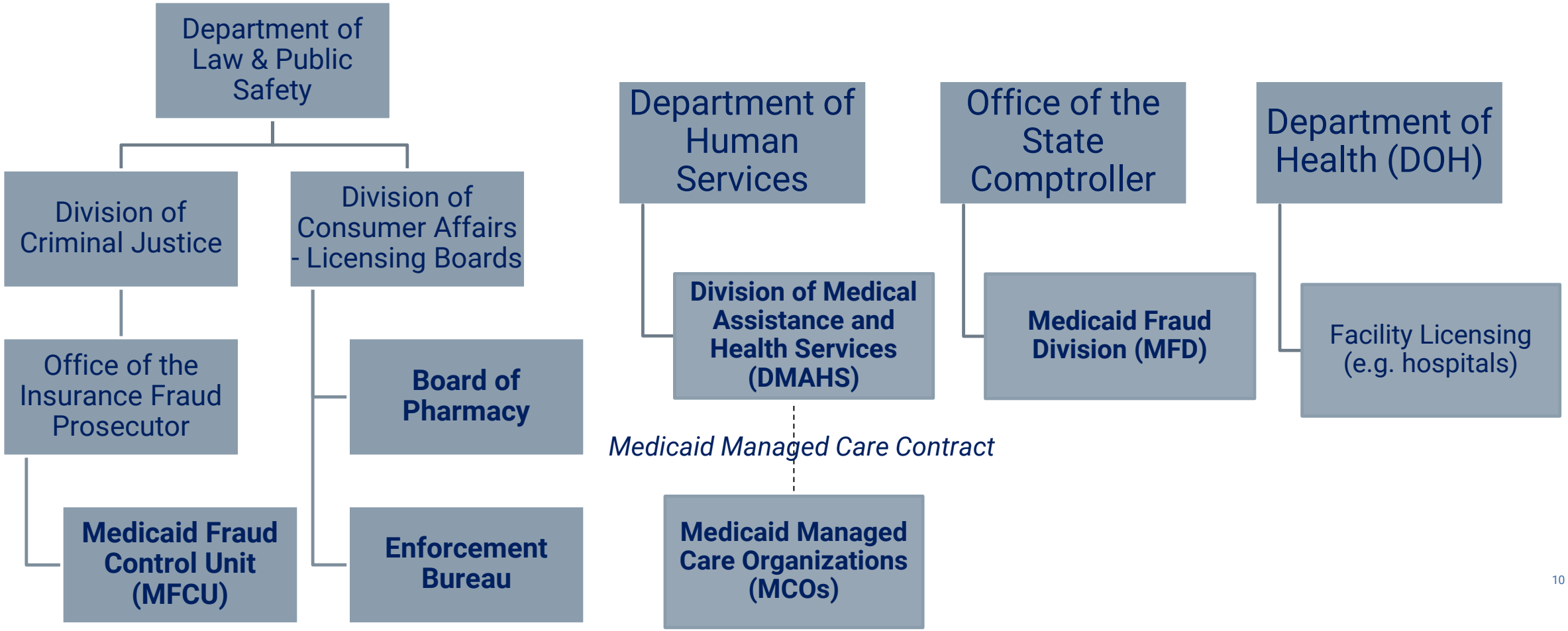
- Medicaid is a joint Federal and State program that provides funding for medical costs and specialized services for eligible individuals.
- Medicaid participation is voluntary. If you want to participate, you must know, accept and abide by the rules and regulations. Your continued participation requires compliance with the regulatory requirements.



MEDICAID (NJ FAMILYCARE)

- Throughout this presentation the words Medicaid and NJ FamilyCare may be used interchangeably.
- NJ FamilyCare is the name of the Medicaid Program in New Jersey, and includes Medicaid, the Children's Health Insurance Program (CHIP), and Medicaid expansion, with services provided through the State and the five Medicaid Managed Care Organizations (MCOs).

NEW JERSEY AGENCY ADMINISTRATION AND MEDICAID OVERSIGHT



GUIDING REGULATIONS, STATUTES, AND NEWSLETTERS

NEW JERSEY BOARD OF PHARMACY (BOP)

Presented by: Khia O'Neal, CPC, CMPA, Supervising Investigator,
Office of the State Comptroller, Medicaid Fraud Division

GUIDING REGULATIONS AND STATUTES

As a New Jersey Medicaid enrolled provider, it is your responsibility to observe all state and federal regulations and statutes regarding Pharmacy Providers.

- State Board of Pharmacy (BOP)
- State Medicaid Agencies
- Food and Drug Administration (FDA)
- Drug Enforcement Administration (DEA)
- The Joint Commission (TJC)

NJ BOARD OF PHARMACY

Purpose:

- To promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy.
- The licensure of pharmacists and the permitting, control and regulation of all pharmacy practice sites in this State that engage in the practice of pharmacy.

NJ BOARD OF PHARMACY

The Board protects the public by:

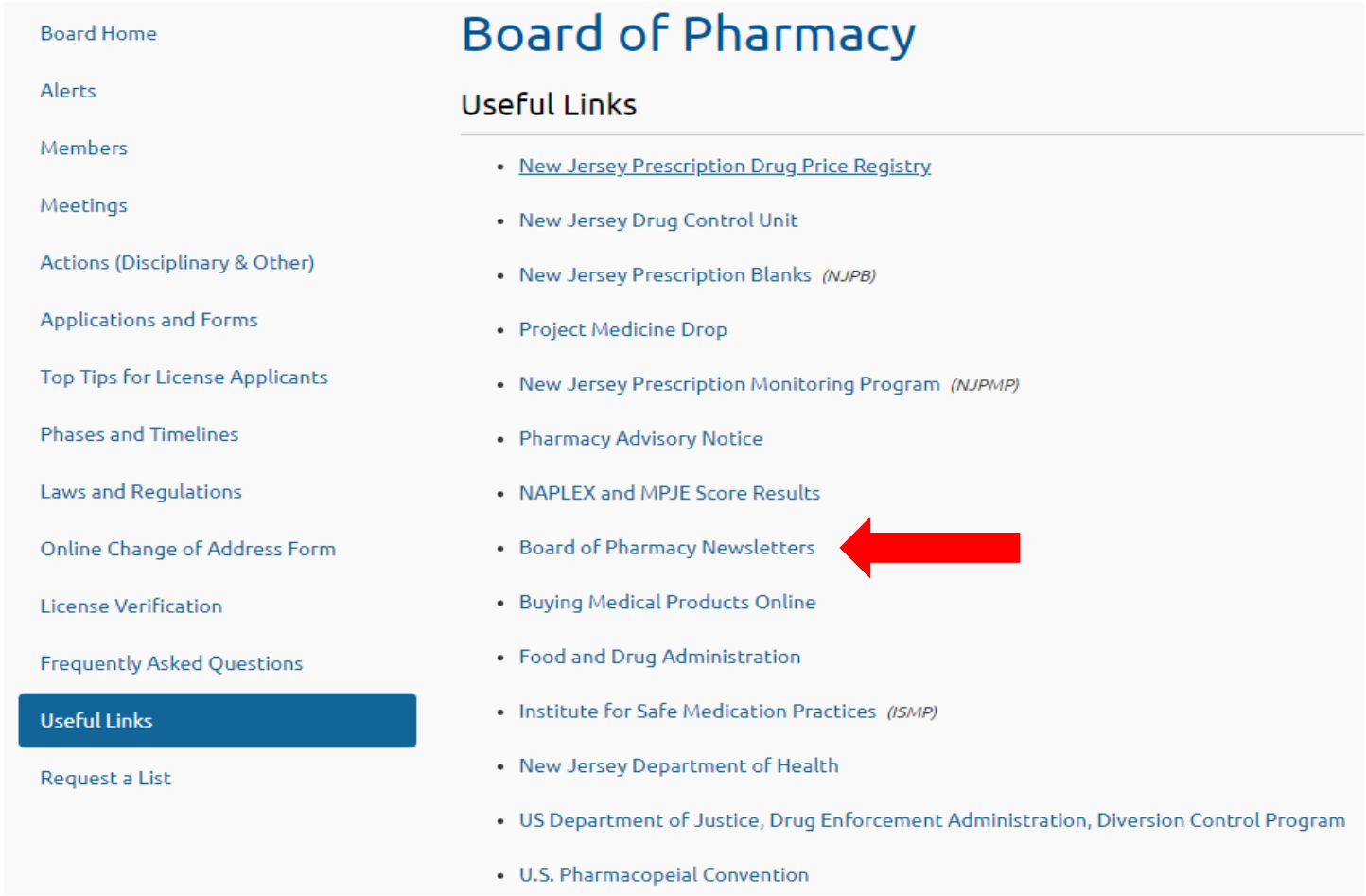
- Making sure that every pharmacist has met all of the necessary requirements for licensure;
- Investigating and disciplining any pharmacist who has not complied with the Board of Pharmacy's laws;
- Enforcing the requirement that every pharmacist continue his/her professional education and training to keep current with the evolving world of pharmacy;
- Requiring that all pharmacies be registered by the State and renew their permits annually;
- Ensuring that patients receive the prescribed medication.

NJ BOARD OF PHARMACY
RELATED REGULATIONS AND STATUTES

- Pharmacy Statutes
- Chapter 39 State Board of Pharmacy Regulations
- Chapter 45H Controlled Dangerous Substances Regulations
- Chapter 45A Subchapter 27 Uniform Prescription Blanks Regulations
- Chapter 45A Subchapter 35 Prescription Monitoring Program Regulations
- Uniform Enforcement Act
- Licensee Duty to Cooperate

BOP NEWSLETTERS

HTTPS://WWW.NJCONSUMERAFFAIRS.GOV/PHAR



BOP ALERTS

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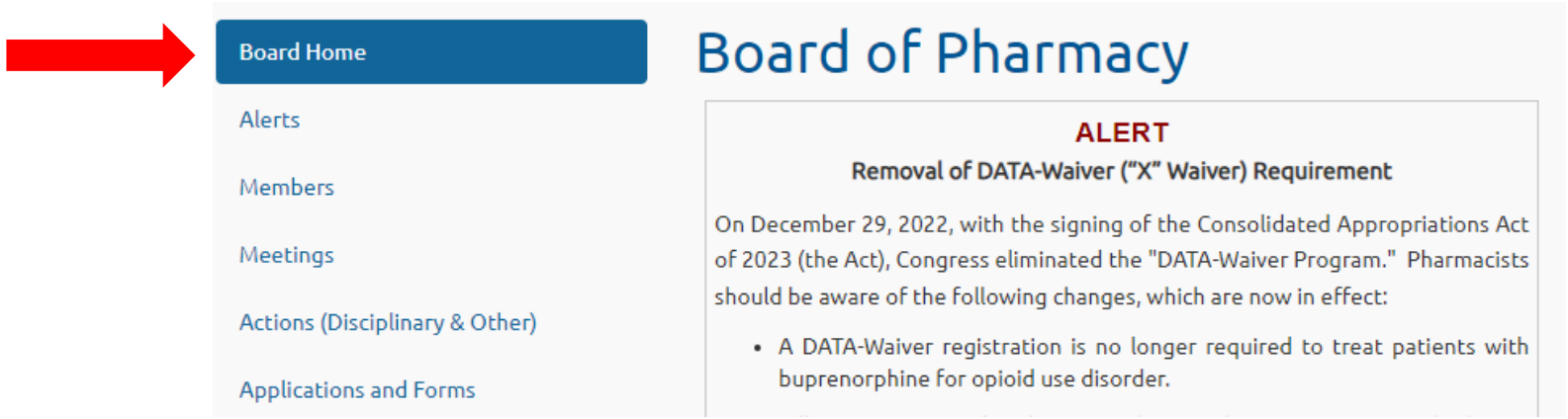
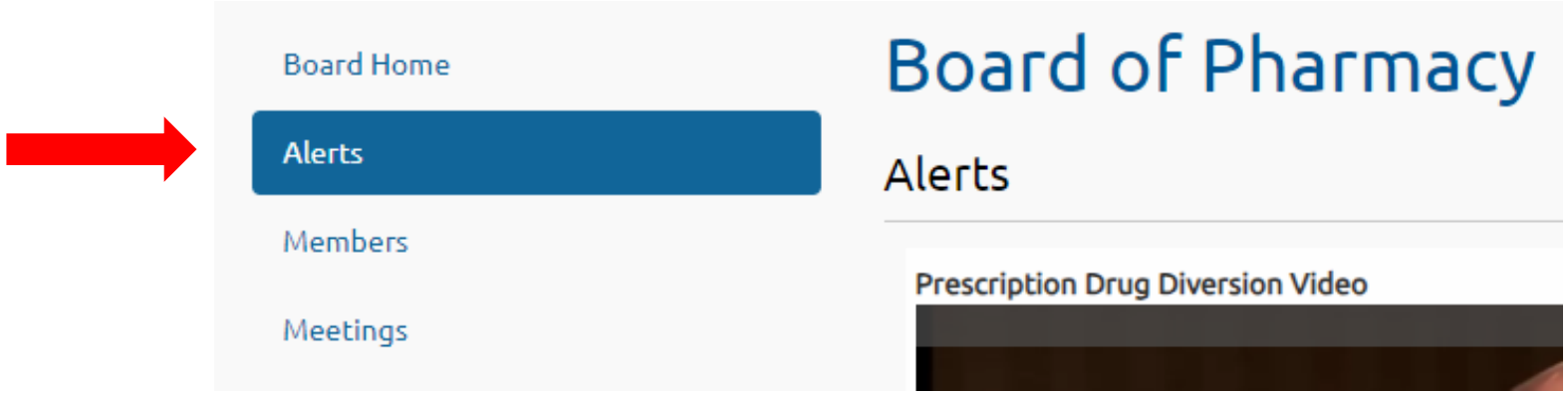




GUIDING REGULATIONS, AND NEWSLETTERS

DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES (DMAHS)

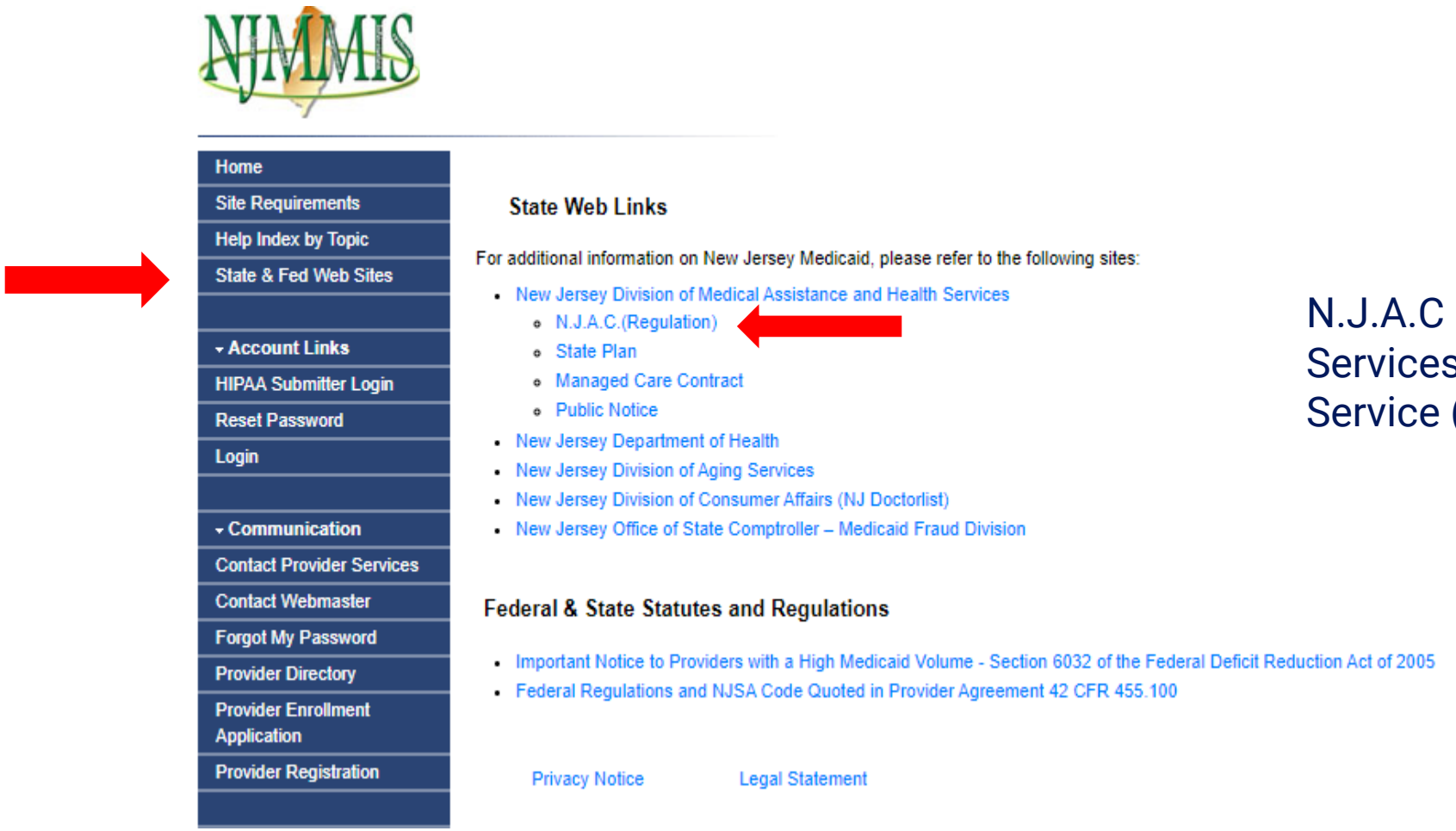
Presented by: Lynda Grajeda, Chief of Managed Care Operations,
Division of Medical Assistance and Health Services

DMAHS

- The Division of Medical Assistance and Health Services (DMAHS) is part of the NJ Department of Human Services.
- DMAHS administers the state-and federally-funded Medicaid program for certain groups of low to moderate income people.

DMAHS REGULATIONS

WWW.NJMMIS.COM



N.J.A.C 10:51 - Pharmaceutical Services Manual - applies to Fee For Service (FFS) pharmacy claims

DMAHS NEWSLETTERS

- Medicaid Newsletters are used to introduce new programs or services, pending regulatory updates or general program guidance.
- Newsletters can be found on www.njmmis.com.
- Newsletters are searchable by provider type and subject.

MEDICAID MANAGED CARE CONTRACT

- DMAHS has a contract with the following Medicaid Managed Care Organizations (MCOs):

  - Aetna Better Health of New Jersey
  - Wellpoint (formerly Amerigroup New Jersey, Inc.)
  - Horizon NJ Health
  - UnitedHealthcare Community Plan
  - Fidelis Care (formerly WellCare Health Plans of New Jersey, Inc.)

MCO SPECIFIC REQUIREMENTS

Presented by: Melissa Brooks, R.Ph., Medicaid Pharmacy Network Integrity,
Horizon NJ Health

MCO SPECIFIC REQUIREMENTS

Provider Portal

Provider Contracts

Provider Manuals

Alerts/Newsletters

Contacts

PROVIDER PORTAL

- Each MCO has dedicated online resources for NJ Medicaid with references to:
  - formulary management
  - prior authorizations
  - policies
  - etc.

- Each PBM/MCO has resources and Help Desk available for pharmacies in their network.

PROVIDER CONTRACTS

- Each PBM/MCO may have their own process to contract, but overall, it will follow this process:
  - Pre-screening of pharmacy – verify store license/licensees, check for sanctions
  - Paperwork packet

PROVIDER CONTRACTS

- Paperwork packet may include:
  - MCO-specific contract
  - Copies of licenses (NJ BOP, PIC, DEA)
  - Certificate of liability insurance
  - W9
  - EFT/payment routing information
  - Other pharmacy/store details (hours of operation, additional available services such as Rx delivery, etc)

PROVIDER CONTRACTS (CONT.)

- Review Phase
  - Verify and check completion of submitted documentation
  - Cross-reference with exclusions databases
- Execution of contract
  - Activate pharmacy NPI in pharmacy systems
  - Notification to pharmacy that it is OK to bill

PROVIDER CONTRACTS (CONT.)

- Monitoring- Exclusions, licensure checks (includes CMS Preclusion List)
- Notifications to MCO - changes in location, ownership, permanent closing

PROVIDER MANUALS

- Each Pharmacy Benefit Manager (PBM)/MCO may have their own manuals available for pharmacy providers
  - Compliance with Federal and State Laws and Regulations
  - Record Retention and Documentation Requirements - as required by DMAHS
  - Billing - Accurate NDC, days supply, etc.
  - Limitations on Collection of Cost Sharing
  - Third Party Liability

ALERTS/NEWSLETTERS

- Refer to MCO websites
- Faxes, emails, phone calls
- Refer to DMAHS Newsletters (available at www.njmmis.com)

CONTACTS

- MCO information contained at the end of the presentation:
  - MCO Pharmacy Help Desk
  - MCO Fraud Hotlines

RED FLAG AREAS

OWNERSHIP AND CHANGES TO OWNERSHIP

Presented by: Amanda Shiber, Policy Advisor, Medicaid Fraud Division and
Lynda Grajeda, Chief of Managed Care Operations, Division of Medical Assistance and Health Services

BOP CHANGES OF OWNERSHIP; ASSET ACQUISITION

N.J.A.C. 13:39-4.5

Type of Change	Requirements
Complete change in ownership	• Within 30 days after the change, the new owner shall submit to the Board a permit application for change of ownership pursuant to N.J.A.C. 13:39-4.1, the permit application fee set forth in N.J.A.C. 13:39- 1.3, and documentation evidencing the change of ownership. • The new owner(s) shall perform an inventory of the pharmacy's controlled substances consistent with the requirements of N.J.A.C. 13:45H-5.4 and 5.5.
Change of registered agents or officers	• Within 30 days after the change, the business entity shall submit to the Board an affidavit indicating the changes that have taken place and any other information requested.

BOP CHANGES OF OWNERSHIP; ASSET ACQUISITION

N.J.A.C. 13:39-4.5

Type of Change	Requirements
Change of stock ownership involving ≥ 10 percent of the outstanding stock of a publicly traded corporation	• Within 30 days after the change, the corporation shall submit to the Board an affidavit indicating the changes that have taken place and any other information requested.
Reallocation of ownership interests among existing owners	• Within 30 days after the change, the owners shall submit to the Board an affidavit explaining the asset reallocation.

BOP CHANGES OF OWNERSHIP; ASSET ACQUISITION

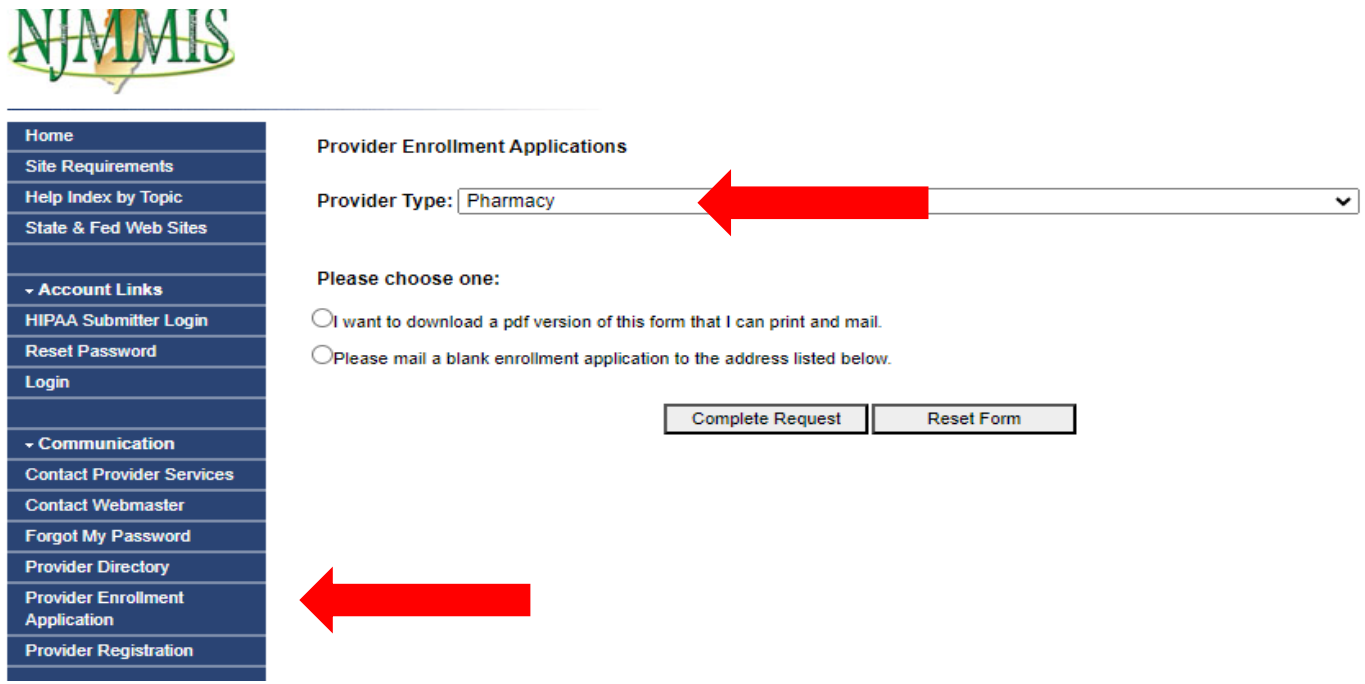
N.J.A.C. 13:39-4.5

- Upon a change in ownership, or sale, transfer or acquisition of the business assets of a pharmacy, the new ownership or entity acquiring the assets shall:
  - take custodial ownership of the previous five years of prescription and profile records of the pharmacy and;
  - ensure that the prescription and profile records are maintained pursuant to N.J.A.C. 13:39-7.6 and 7.19 after the date of acquisition.

- The letter the Board sends to pharmacies to confirm changes of ownership now contains language reminding pharmacies of their obligation to notify Medicaid of such changes
  - that message can be found on the Board's Alerts page

DMAHS - OWNERSHIP

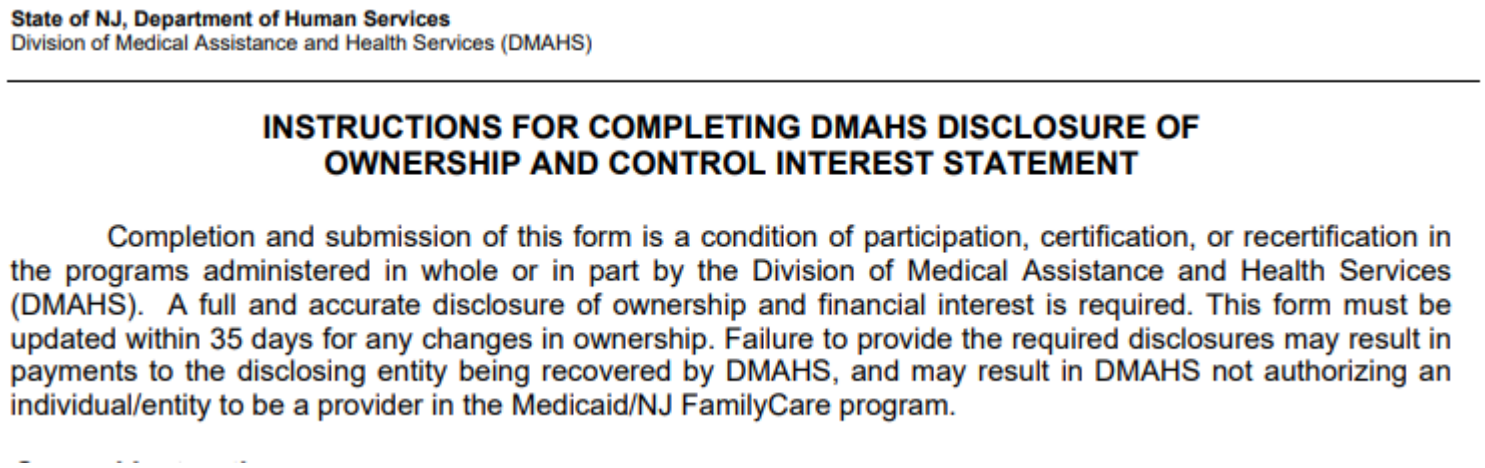
To become a New Jersey Medicaid provider,
ownership must be disclosed on the Pharmacy Provider Enrollment Application
Disclosure of Ownership and Control Interest Statement form



Or select 21st Century Cures, which is a separate option on the drop-down list.

DMAHS DISCLOSURE OF OWNERSHIP AND CONTROL INTEREST STATEMENT

- Page 13 of the Pharmacy Provider Application
  - Defines ownership
  - Required for both new applications and changes of ownership applications



State of NJ, Department of Human Services
Division of Medical Assistance and Health Services (DMAHS)

INSTRUCTIONS FOR COMPLETING DMAHS DISCLOSURE OF OWNERSHIP AND CONTROL INTEREST STATEMENT

Completion and submission of this form is a condition of participation, certification, or recertification in the programs administered in whole or in part by the Division of Medical Assistance and Health Services (DMAHS). A full and accurate disclosure of ownership and financial interest is required. This form must be updated within 35 days for any changes in ownership. Failure to provide the required disclosures may result in payments to the disclosing entity being recovered by DMAHS, and may result in DMAHS not authorizing an individual/entity to be a provider in the Medicaid/NJ FamilyCare program.

DMAHS TIMELY CHANGES OF OWNERSHIP NOTIFICATIONS

N.J.A.C. 10:51-1.2(b)

- Requires that you notify the Medicaid/NJ FamilyCare (NJFC) Program of any change in ownership by submitting an updated Ownership Disclosure form, from the Pharmacy Provider Enrollment Application, to Gainwell Technologies Provider Enrollment Unit to initiate a review process.
  - Pharmacy Provider Enrollment Applications may be found at www.njmmis.com.
  - 21st Century Cures Act Application for Individual NJ Family Care Health Plan Providers found at www.njmmis.com.
  - The Disclosure of Ownership document is available on the NJMMIS website (under Forms & Documents)
- Questions can be directed to Gainwell Technologies Provider Enrollment Unit at 609-588-6036 or NJMMISproviderenrollment@gainwelltechnologies.com.
- Failure to do so may result in action by the Medicaid program, which may include monetary recovery, penalty assessment, and/or prohibition on your participation as a Medicaid provider.

RECORD KEEPING, AND INVOICE MANAGEMENT

Presented by: Kimberly Mateo, BS, CPhT , Supervisor, Pharmacy Investigations,
Fidelis Care

RECORD KEEPING

- N.J.S.A. 30:4D-12(f): Providers shall agree to the examination and in making copies of any books and records that relate in any way to services rendered to any recipient and permit the inspection of the premises.
- N.J.A.C. 10:49-9.8(b)(3): Providers shall agree that where such records do not document the extent of services billed, payment adjustments shall be necessary.

RECORDS RETENTION TIMELINES

The New Jersey statute and administrative code that speak to record retention timelines are:

- N.J.S.A. 30:4D-12(d)
- N.J.A.C. 10:49-9.8(b)(1)

MCO contracts indicate:

- Records must be retained for the later of ten (10) years from the date of service or after the final payment is made under the provider contract/subcontract and all pending matters are closed.

Timelines may vary depending upon the source.
Follow the source with the greatest length of time that pertains to you!

RECORDS RETENTION

N.J.S.A. 30:4D-12

- Requires the following information be maintained:
  - Full name of the recipient to whom the service was rendered
  - Date of service
  - Nature and extent of service rendered
  - Any additional information that may be required by regulation (for example: BOP, DMAHS, FDA, DEA)

INVOICE MANAGEMENT/RECORDS RETENTION
(MCO PROVIDER MANUALS)

- Pharmacies shall keep and maintain wholesaler, manufacturer, and distributor invoices and other purchase invoices and documents for prescription drugs and medical supplies for a minimum of ten (10) years.
- Records must indicate:
  - Price
  - Drug name
  - Dosage form
  - Strength
  - NDC
  - Lot number and quantity

INVOICE MANAGEMENT/RECORDS RETENTION
(MCO PROVIDER MANUALS)

- Pharmacies shall also maintain adequate records to validate purchases from wholesalers (proof of payment)
- Invoices and documentation must substantiate that the prescription drugs or medical supplies dispensed were purchased from an authorized source:
  - National Association of Boards of Pharmacy – Accredited Drug Distributor (formerly VAWD)
  - Licensed as a drug wholesale distributor in NJ

  *Adherence to additional track and trace requirements as mandated by the Drug Supply Chain Security Act (DSCSA) will be in effect November 2024

INVENTORY TRANSFERS
(MCO PROVIDER MANUALS)

- In some cases, pharmacies may transfer inventory.
- The transfer of products/medical supplies from another licensed pharmacy must be verified and documented as originating from a NABP Accredited Drug Distributor.
- All records involved in the transfer must be maintained and accessible for ten (10) years.

RECORDS RETENTION – INVENTORY TRANSFERS
(MCO PROVIDER MANUALS)

- These records shall be contemporaneous with the transfer and shall include:
  - Name of the prescription drug or medical supply
  - Dosage form
  - Strength
  - NDC
  - Lot number
  - Quantity
  - Date transferred
  - The supplier/manufacturer's name, address and registration number
  - Additional DSCSA requirements if a transfer is not patient specific

BEST PRACTICES

CMS PHARMACY SELF-AUDITING TOOL

- Pay attention to NDCs of medications that appear on wholesale invoices, and receipts
  - Compare NDCs purchased from wholesalers to NDCs appearing on claims for that drug
- Ensure wholesale distributors are reputable
  - Check NABP Accredited Drug Distributor status
  - If no NABP Accredited Drug Distributor status, ensure wholesalers are registered with the DEA and appropriate State controlled substance agency
  - In NJ the agency overseeing wholesalers is Department of Health (DOH)
- Do drug claims exceed purchases? If so, this is an invoice shortage.
  - This may occur if there is not enough of a drug or if records do not exist for an NDC purchase.
- Maintain required product tracking information as required by DSCSA

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA)

Presented by: Tony Qi, PharmD, RP, Supervising Investigator/Section Supervisor,
Office of the Attorney General, Division of Consumer Affairs Enforcement Bureau

DSCSA - WHAT IS THE DSCSA?

- The DSCSA, Drug Supply Chain Security Act, enacted in 2013, preempts a 50-state patchwork of pedigree requirements to create one federal traceability framework for prescription medicines.
- The DSCSA sets out a 10-year timeline to build an electronic, interoperable system for the exchange of transaction documentation [transaction information (TI), transaction history (TH), and transaction statements (TS)] to enable the tracing of prescription medicines throughout the pharmaceutical supply chain.

DSCSA - QUIZ

1. Is the Prescription Drug Marketing Act (PDMA) pedigree provision still in effect?

2. Which drugs do and do not fall under the DSCSA requirements for product tracing, product identifier, authorized trading partner, and verification?

3. Who must comply with DSCSA requirements for product tracing, product identifier, authorized trading partner, and verification?

4. When a pharmacy sells a product to another pharmacy, do the DSCSA product tracing requirements related to transaction history, transaction information, and transaction statements apply?

DSCSA

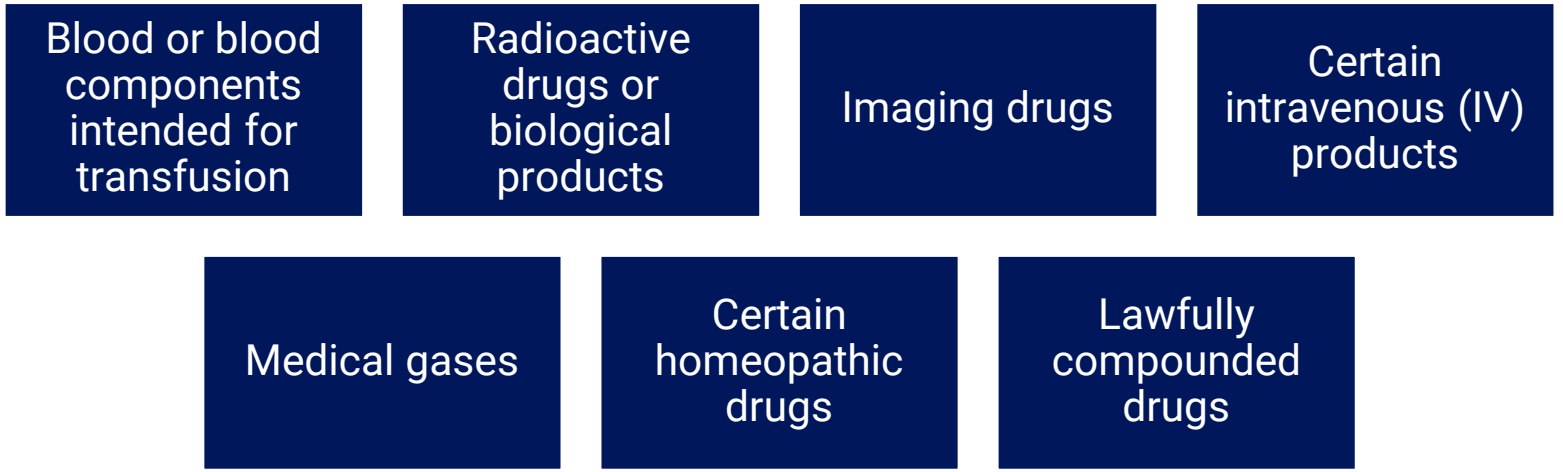
Is the Prescription Drug Marketing Act (PDMA) pedigree provision still in effect?

- No. The “pedigree” provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (added by the PDMA of 1987) no longer exists and is no longer in effect.
- Section 204 of the DSCSA removed the drug pedigree language and replaced it with new language in section 503(e) of the FD&C Act, which pertains to new licensing requirements and uniform national standards for wholesale distribution of prescription drugs.

DSCSA

Which drugs do and do not fall under the DSCSA requirements for product tracing, product identifier, authorized trading partner, and verification?

- Product means “a prescription drug in finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution).”
- The section 582 requirements do not apply to:



DSCSA

Who must comply with DSCSA requirements for product tracing, product identifier, authorized trading partner, and verification?

- Drug manufacturers, repackagers, wholesale distributors and dispensers (primarily pharmacies)

DSCSA

When a pharmacy sells a product to another pharmacy, do the DSCSA product tracing requirements related to transaction history, transaction information, and transaction statements apply?

- Yes, except for sales by a dispenser to another dispenser to fulfill a specific patient need.
- More information can be found in sections 581(19) and 582(d)(1)(A)(ii) of the FD&C Act.

DSCSA – KEY ATTRIBUTES

- Intent to protect patients from drug products that are harmful and ineffective by tracking the product from the manufacturer to patient use by protecting the product integrity.
- Establish nationwide uniform and consistent standards for maintaining quality in prescription drug distribution.
- Require prescription drug supply trading partners to build an electronic, interoperable system to track and trace drug products throughout the supply chain.
- Enhance a trading partner's capability to identify and segregate a suspect and illegitimate product in the supply chain.

DSCSA – MARKET PLACE SCHEME

- Theft-2012 Miami 14 million Specialty Drug
- Counterfeit-2022 Gilead Science HIV Medications
- Adulterated-2022 United States v. Lazaro Hernandez
- Diversion Schemes –Gray Market
- Drug Shortages

DSCSA

BILLING PRACTICES

Presented by: Mona Kripalani, RPh, MBA, Plan Pharmacy Director – New Jersey,
UnitedHealthcare Community & State

RESPONSIBLE BILLING PRACTICES

- Pharmacies are required to have a product in stock at the pharmacy prior to submitting a claim for the product.
- All claims submissions shall contain the National Drug Code (NDC) of the product dispensed.
  - N.J.A.C. 10:51-1.24(b)2
  - MCO Provider Manuals
- Only the NDC of the actual product dispensed shall be submitted on the claim. Use of a similar NDC of a product not dispensed is not permissible.
  - Important to ensure the State receives the appropriate rebate to which the State is entitled

RESPONSIBLE BILLING PRACTICES

Refill Practices – do not:

- auto-refill, or push-bill without patient consent/request, or when prohibited
  - NJMMIS Newsletter Volume 29 No. 17 – outlines requirements for New Jersey
- use financial incentives to influence patients

Point of Sale Overrides:

- Ensure any information provided for adjudication of a prescription claim is accurate.
- Prior authorization justification required from the prescriber must be provided by the prescriber, not the pharmacy.
- For MCO claims, any override codes permitted in pharmacy claims for refill too soon, lock-in, DUR, DAW, and other prior authorizations are used only when justified, and when criteria are met.

RESPONSIBLE BILLING PRACTICES (COMPOUNDS)

- Pharmacies shall keep and maintain any compound recipe worksheets identifying ingredients used in a compounded prescription drug.
- Pharmacies must submit claims with all ingredients included in each compound and may only submit claims with the NDC associated with the actual ingredients filled/dispensed.
- N.J.A.C. 10:51-1.8 – Compounded Prescriptions
- NJMMIS Newsletter Volume 23 No. 13 - provides information on non-covered active pharmaceutical ingredients (APIs)

RESPONSIBLE BILLING PRACTICES - REVERSALS

- N.J.A.C 13:39-7.16 The Board of Pharmacy identifies a prescription medication to be considered abandoned when a prescription is prepared and made available for dispensing by the pharmacy but is not dispensed to the patient within two weeks

- Providers should reverse point-of-sale payments for prescriptions not received by a member or responsible party within fourteen (14) days of the filling of and billing for the prescription.

BEST PRACTICES

CMS PHARMACY SELF-AUDITING TOOL

- Quantities and days' supply should align with claims submitted.
- The NDC dispensed must match the NDC on the claim.
- For compounded medications, bill the correct quantities used.
- Report potential stockpiling/diversion activities.
- Use the smallest available packaging and document when larger packaging is used.
- If a Medicaid overpayment is identified:
  - Self-disclose to the Medicaid Fraud Division
- Follow proper billing procedures to return medications to stock
  - Ensure that billing for the claims is reversed

CONTROLLED SUBSTANCES AND NJPMP

Presented by: Michael Alfano, Sr. SIU Investigator,
Aetna Better Health of New Jersey

CONTROLLED SUBSTANCES

- DEA
  - Controlled Substances Act (CSA)
- DCA Drug Control Unit :
  - Controlled Dangerous Substances Statutes
  - Chapter 45H Controlled Dangerous Substances Regulations
- NJ Prescription Monitoring Program (NJPMP)
  - NJPMP Statutes
  - Chapter 45A Subchapter 35 Prescription Monitoring Program Regulations

CONTROLLED SUBSTANCES – BEST PRACTICES

- Ensure hiring procedures include adequate background checks
- Ensure an accurate and ongoing inventory of controlled substances
  - Complete a physical inventory of all controlled substances every 2 years (Drug Enforcement Agency (DEA) requirement)
- Mitigate physical security risks through access restrictions
- Pharmacists-in-charge (PICs) responsibilities include:
  - Complete physical inventory for incoming and outgoing PIC
  - Ensure current licensure of the pharmacy and its personnel
  - Adhere to registration requirements of the Controlled Substances Act
  - Comply with the NJ State Prescription Drug Monitoring Program
  - Comply with the Medicaid lock-in program

CONTROLLED DRUGS – NEW JERSEY PRESCRIPTION MONITORING PROGRAM (NJPMP)

- Overseen by the New Jersey Division of Consumer Affairs
  - Established pursuant N.J.S.A. 45:1-45, et, seq.

- A statewide database - collects prescription data on the following drugs dispensed in outpatient settings in New Jersey, and by out-of-State pharmacies dispensing into New Jersey:
  - Controlled Dangerous Substances (CDS)
  - Human Growth Hormone (HGH)
  - Gabapentin

NJ Rx PMP
NEW JERSEY PRESCRIPTION MONITORING PROGRAM

CONTROLLED DRUGS –NJPMP

- Pharmacies are required to report information to the NJPMP on a daily basis
  - prescription must be reported no more than one business day after the date the prescription was dispensed.
- The NJPMP does NOT collect any prescription records from inpatient facilities – such as hospitals, long-term care facilities, or any other location where a patient is provided with 24-hour care from a supervised healthcare professional.
- Medication-Assisted Treatment and Substance-Use Disorder Treatment Facility information is currently protected under federal law (42 CFR, Part2) and is not shared with the NJPMP.

NJ Rx PMP
NEW JERSEY PRESCRIPTION MONITORING PROGRAM

CONTROLLED DRUGS –NJPMP ACCESS

- CDS-registered prescribers, authorized prescriber delegates, and pharmacists who are licensed by the State of New Jersey and whose licenses are in good standing.
- NJ-licensed mental health practitioners providing treatment for substance abuse to patients at a residential or outpatient substance abuse treatment center licensed by the Department of Health.
- State & County Medical Examiners who certify that the request is for the purpose of investigating a death.
- Designated representatives of the State Medicaid program or any of the State Boards of Healthcare Professionals who certify they are engaged in a bona fide investigation.
- Federal, State, or municipal law enforcement officers acting pursuant to a grand jury subpoena or court order who certify they are engaged in a bona fide investigation.

CONTROLLED DRUGS –NJPMP PURPOSE

Healthcare Professionals (Program Users)

- Support clinical decisions
- Identify and minimize multiple prescriber/pharmacy events and overprescribing
- Identify patients at risk for developing opioid use disorder (OUD)

State Administration

- Enable data-driven policy and collaboration
- Develop targeted interventions
- Strengthen drug-related investigations with evidence-based intelligence

NJ Rx PMP
NEW JERSEY PRESCRIPTION MONITORING PROGRAM

COMPLIANCE AND THE MEDICAID FRAUD DIVISION

Presented by: Tracy Livingston, Assistant Director, Data and Fiscal,
Office of the State Comptroller, Medicaid Fraud Division

SIX STEPS TOWARDS COMPLIANCE (BEST PRACTICES)

1. Ensure that claims submitted are for the actual NDC of the product dispensed.
2. Quantity and days supply must reflect the prescriber’s order
3. Maintain responsible billing practices
4. Keep all prescription files/signature logs organized and complete
5. Reverse payment for prescriptions not picked up
6. Bill Medicaid as a payer of last resort

ABOUT THE MEDICAID FRAUD DIVISION (MFD)

- New Jersey "Medicaid Program Integrity and Protection Act", N.J.S.A. 30:4D-53 et seq. established the Office of the Medicaid Inspector General to detect, prevent, and investigate Medicaid fraud and abuse, recover improperly expended Medicaid funds, enforce Medicaid rules and regulations, audit cost reports and claims, and review quality of care given to Medicaid recipients.

- These functions, powers and duties were later transferred to the Office of the State Comptroller (OSC), and are carried out by the Medicaid Fraud Division (MFD).

ABOUT THE MEDICAID FRAUD DIVISION (MFD)

The Medicaid Fraud Division:

- Performs program integrity functions;
- Conducts audits and investigations of potential fraud, waste and abuse by providers and recipients; and
- Coordinates program integrity oversight efforts among all State agencies that provide and administer Medicaid services and programs.

ABOUT THE MEDICAID FRAUD DIVISION (MFD)

The Medicaid Fraud Division also:

- Works to recover improperly expended Medicaid funds;
- Enforces Medicaid rules and regulations;
- Audits cost reports and claims;
- Reviews the quality of care given to Medicaid recipients; and
- Excludes or terminates providers from the Medicaid program where necessary.

CONSEQUENCES

Non-compliance with Medicaid rules, standards and regulations regarding service may constitute acts of fraud, waste or abuse of Medicaid funds.

WHAT IS: FRAUD, WASTE, AND ABUSE?

Presented by: Ryan Thuman, Senior Investigator, Special Investigations Unit, Fidelis Care

FRAUD
N.J.S.A. 30:4D-55

Fraud

- An intentional deception or misrepresentation made by any person with the knowledge that the deception could result in some unauthorized benefit.

WASTE

- Waste
  - Generally understood to encompass overutilization or the misuse of resources.
  - Not *usually* considered a criminal act.
  - Considered a legal violation for civil purposes and can result in a recovery of an overpayment, debarment from the Medicaid program and penalties

ABUSE
N.J.S.A. 30:4D-55

- Abuse
  - Provider practices that are inconsistent with proper, sound fiscal, business, or professional or service delivery practices
  - Provider practices that result in:
    - unnecessary costs to or improper payment by Medicaid, or
    - reimbursement for services that are not necessary, not approved, not documented, that are outside those specifically authorized

WASTE AND ABUSE - PROFESSIONAL DUE DILIGENCE

Business practices that result in **waste and abuse** can rise to the level of **fraud:**

- Providing service without proper authorization (unless it is emergent care)
- Using unlicensed, unqualified, or untrained staff
- Inaccurate / incomplete documentation of service
- Billing for undocumented / unsubstantiated services
- Insufficient internal checks and balances

CIVIL MEDICAID FRAUD, WASTE AND ABUSE CONSEQUENCES

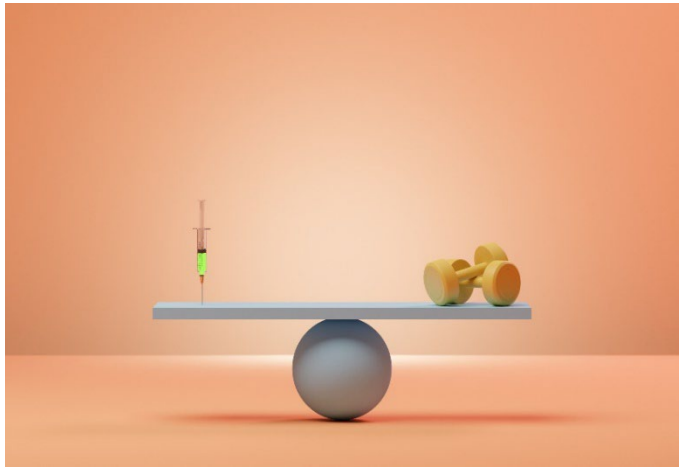
- Civil judgments and liens
- Exclusion from the Medicaid/Medicare programs
- Referral for criminal prosecution
- Restitution/Recovery of overpayments
- Additional penalties in addition to repaying Medicaid overpayments

AUDIT AND INVESTIGATION FINDINGS: EXAMPLES

Presented by: Mary Crane, DC, AHFI, Investigator Lead, Wellpoint, and
Vira M. Jaskir, RPh, CPIP, Investigator, Office of the State Comptroller,
Medicaid Fraud Division

EXAMPLE: OZEMPIC PRESCRIBING

- Outlier prescribers were identified for high volumes of Glucagon-Like Peptide-1 (GLP-1) prescriptions.
- GLP-1 Receptor Agonists have gained popularity because of their weight loss effects.
  - Ozempic, Wegovy & Saxenda are all GLP-1 receptor agonists.
  - Wegovy and Saxenda are approved for weight loss, but Ozempic is not.
- Medical records were requested to confirm the members had a diagnosis of diabetes and substantiate the prescription.



EXAMPLE: OZEMPIC PRESCRIBING

Providers:

- Refused to respond to the records request.
- Charged the patient cash so they could prescribe for them.
- Submitted records which identified members were treated for weight loss and did not have a diabetes diagnosis. In these instances, the prior authorization for the prescription was improperly filled out and submitted, stating the member had diabetes.

EXAMPLE: OZEMPIC PRESCRIBING

- Some providers were identified with online telehealth weight loss clinics:
  - Advertised cash visits and helped with insurance prior authorizations.
  - Had providers come forward alleging they used their NPI to write prescriptions without their knowledge or authorization.
  - Authorizations showed the member had a diagnosis of diabetes, when they did not, meaning they falsified the authorization to get it approved by insurance.

EXAMPLE: OUT OF STATE LICENSURE

- Several pharmacies are dispensing medications out of state.
- Some are registered as mail order pharmacies, but do not hold valid licensure in some of the states they are mailing medications to.
  - For example, Feelgood Pharmacy located in NJ

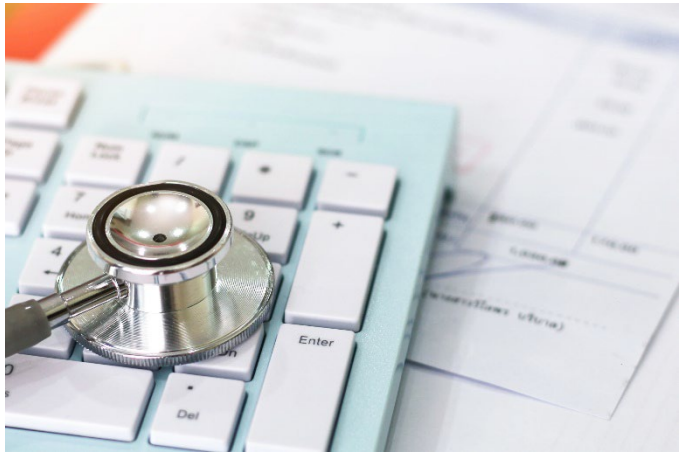
EXAMPLE: OUT OF STATE LICENSURE

- Dr. Diet (telehealth provider) in CT, writes a prescription for Ozempic and sends to Feelgood Pharmacy.
- Member is in FL. Feelgood pharmacy fills prescription and mails it to Member in FL.
- Feelgood pharmacy is licensed in NJ, as well as CT, GA, VA, AL, and KY.
- Feelgood pharmacy does not hold Pharmacy Licensure active in the remaining states across the U.S. Therefore, Feelgood pharmacy should NOT be filling and mailing prescriptions for members out of state, where they do not hold active licensure.

EXAMPLE: INVENTORY AUDIT

Background:

- MFD opened a case based on high volume of Medicaid claims.



MFD Pharmacy Inventory Case:

- An inventory audit showed insufficient quantities of drugs in its inventory to support its Medicaid claims for these same drugs.

EXAMPLE: INVENTORY AUDIT

The OAL Hearing:

- The pharmacy formally challenged MFD's investigative findings by requesting a contested case hearing in the Office of Administrative Law (OAL).
- MFD presented to the judge the legal and real-world significance of a pharmacy dispensing a bio-equivalent product while submitting claims to and being paid by Medicaid for another product.

EXAMPLE: INVENTORY AUDIT

OAL Hearing Outcome:

- The pharmacy agreed to pay the Medicaid program the total amount of the principal amount plus an additional payment of 6% interest on the principal amount.
- Settlement agreement was signed in which it agreed to act in full compliance with all applicable state and federal rules and regulations, including but not limited to submitting only claims that accurately and completely reflect the services provided and medications purchased and dispensed, along with their corresponding NDC numbers.

EXAMPLE: INVENTORY AUDIT

Applicable Regulations/Policy and Procedures:

- The pharmacy failed to have the necessary supporting documentation in violation of N.J.S.A. 30:4D-12(d) and N.J.A.C. 10:49-9.8, for claims which did not contain the National Drug Code ("NDC") of the actual drug dispensed, in violation of N.J.A.C, 10:51-1.24(b)(2), and Medicaid MCO's policies.

EXAMPLE: EXCLUDED INDIVIDUALS/INVENTORY AUDIT

Background:

- MFD opened a case as follow-up to a previous case in which the owner/pharmacist had pleaded guilty to purchasing prescriptions (including HIV drugs) from indigent patients in order to bill for medications, but never dispensed them.

MFD Pharmacy Inventory Case:

- An inventory audit was conducted as a follow-up to the previous case

EXAMPLE: EXCLUDED INDIVIDUALS/INVENTORY AUDIT

Case Outcome:

- Despite the many signed testimonials by recipients of receiving medications, the pharmacy was not able to provide documentation of having purchased the medications billed to the Medicaid Program.

The Settlement:

- A settlement agreement was signed and the pharmacy agreed to repay the Medicaid program for all prescription claims, which could not be supported by wholesaler invoices.
- The pharmacy also agreed to act in full compliance with all applicable state and federal laws and regulations and agreed to only submit claims for services provided for which it possesses sufficient documentation to support such claims.

EXAMPLE: EXCLUDED INDIVIDUALS/INVENTORY AUDIT

Applicable Regulations/Policy and Procedures:

- The pharmacy failed to have the necessary supporting documentation in violation of N.J.S.A. 30:4D-12(d) and N.J.A.C. 10:49-9.8, for claims which did not contain the National Drug Code ("NDC") of the actual drug dispensed, in violation of N.J.A.C, 10:51-1.24(b)(2), and Medicaid MCO's policies.

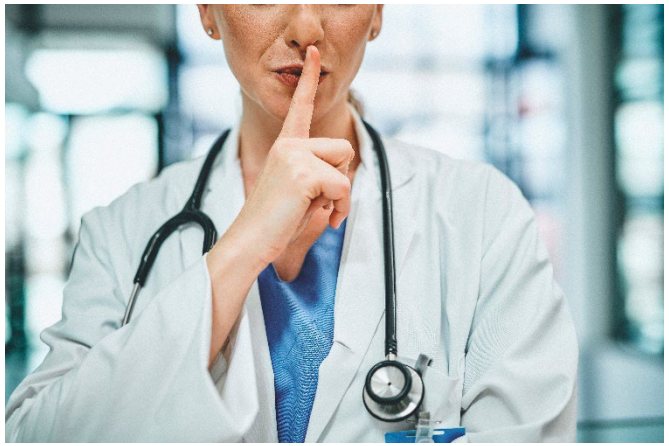
MEDICAID FRAUD CONTROL UNIT (MFCU)

Presented by: Detective Michael Rosati,
Medicaid Fraud Control Unit

MEDICAID FRAUD CONTROL UNIT (MFCU)

Medicaid Fraud is a serious crime.

- The MFCU, within the Office of the Insurance Fraud (OIFP) is the criminal oversight entity.



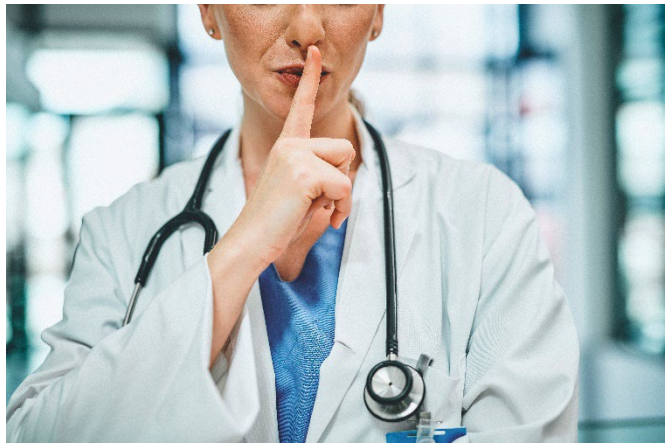
- MFCU investigates and prosecutes Medicaid Fraud.

- The MFCU utilizes attorneys, investigators, nurses, auditors and other support staff to police the Medicaid system.

MEDICAID FRAUD CONTROL UNIT (MFCU)

The MFCU investigates and prosecutes alleged criminal actions:

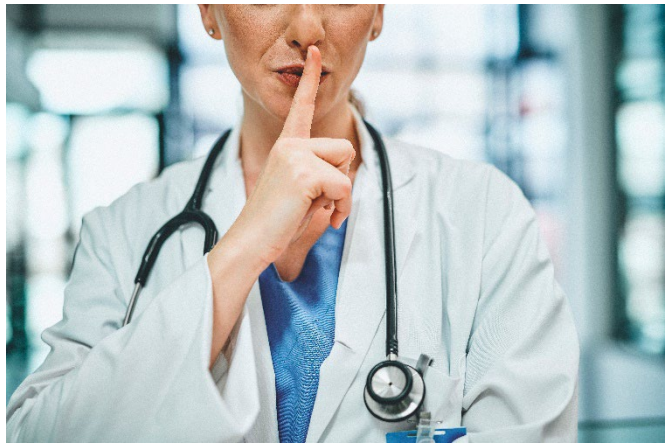
- Allegations of physical abuse to beneficiaries.
- Healthcare Providers who are suspected of defrauding the Medicaid Program.
- Fraudulent activities by providers against the Medicaid program.
- Fraud in the administration of the program.
- Fraud against other federally or state funded health care programs where there is a Medicaid nexus.



CRIMINAL HEALTH CARE CLAIMS FRAUD

N.J.S.A. 2C:21-4.3

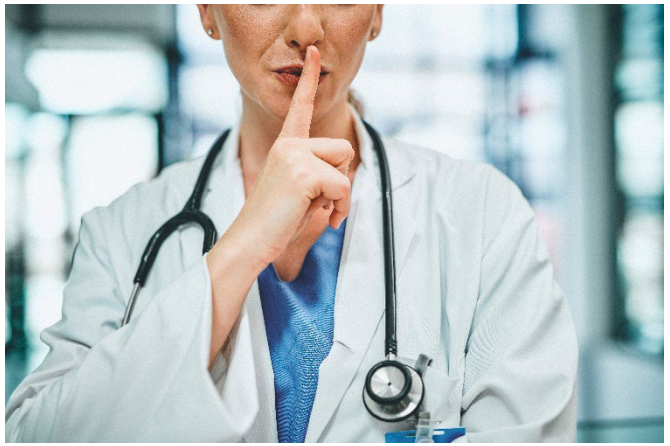
- It is illegal to submit a false claim to the Medicaid program or an insurance company in order to be paid for health care services which were not received or provided.
- Punishable by up to 10 years in state prison
- In addition to all other criminal penalties allowed by law, a violator may be subject to a fine up to five times the amount of any false claims.
- Suspension or debarment from government funded healthcare programs
- Forfeiture of professional license



FALSE CLAIMS

Did you know…

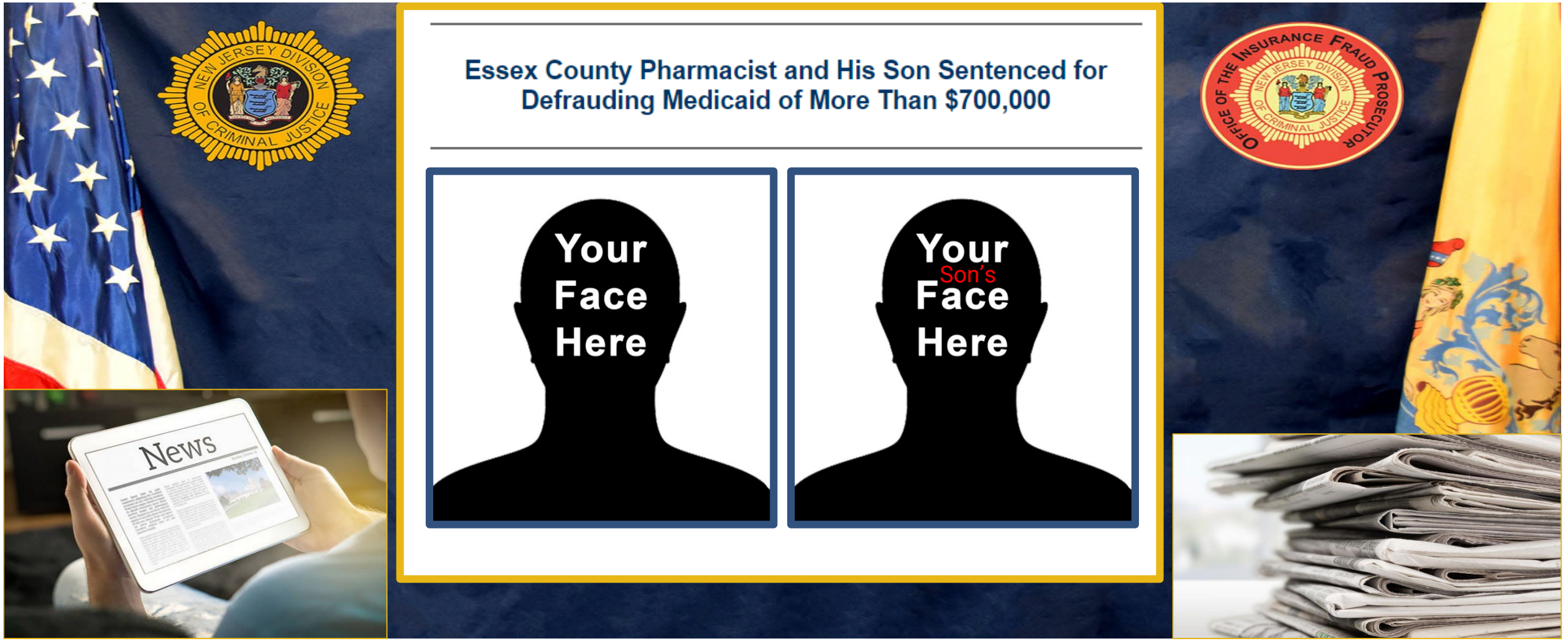
- If you are a practitioner and hold a professional license, you only need to submit one false claim to be convicted.



- Willful ignorance of the truth or falsity of a claim is not a defense.

- You can be found guilty of Health Care Claims Fraud even if your claims were not intentionally fraudulent.

MEDICAID FRAUD: IN THE NEWS



MEDICAID FRAUD: CASE STUDY

- Pharmacy owner and his son engaged in a “cash-for-scripts” fraud scheme.

- Large scale/multi-agency investigation:
  - New Jersey MFCU;
  - U.S. Food and Drug Administration’s Office of Criminal Investigations; and
  - Local city police department.

- 13 defendants pleaded guilty for their roles in the scheme:
  - Clinic owner
  - Pharmacist
  - Pharmacy technician
  - Medicaid beneficiaries

MEDICAID FRAUD: CASE STUDY

- Pharmacy Owner and his son both pleaded guilty to second-degree health care claims fraud.

- Son, also pleaded guilty to third-degree witness tampering.
  - Owner and son each sentenced to 3 years in state prison.
  - Owner surrendered his pharmacy license.
  - 8 year Medicaid exclusion.
  - Restitution and civil penalties totaling $1.1 million.

Bottom line:

Ignorance of the law excuses no one.

It is the provider's responsibility to know the laws.

MEDICAID FRAUD DIVISION: ACTIONS, INELIGIBLE PROVIDERS, SELF-DISCLOSURES, AND THIRD PARTY LIABILITY

Presented by: Melanie Donnelly, Advisor, Administration and MCOs,
Office of the State Comptroller, Medicaid Fraud Division

MFD RECOVERY ACTIONS

Once an overpayment has been identified as a result of an investigation or audit, MFD initiates actions for recoupment of improperly paid funds:

- ✓ MFD will send a Notice of Estimated Overpayment or Notice of Intent and, if necessary, a Notice of Claim
- ✓ MFD may add penalties, including false claim penalties between $13,508 and $27,018 per claim
- ✓ MFD may file a Certificate of Debt on real estate property owned by a provider/owner of business
- ✓ MFD may seek a Withholding of future Medicaid payments until the overpayment is satisfied

INELIGIBLE PROVIDERS

- An ineligible provider is someone who is excluded from participation in Federal or State funded health care programs. Debarred, disqualified, suspended, or excluded providers are considered ineligible providers.
- Any products or services that an ineligible provider directly or indirectly furnishes, orders or prescribes are not eligible for payment under those programs (N.J.A.C. 10:49-11.1(b)).
- It is incumbent upon providers to perform Ineligible Provider Checks, upon hire and monthly thereafter:
  - NJMMIS Newsletter Volume 26, Number 14

MEDICAID INELIGIBLE PROVIDER LIST REQUIREMENTS

1. State of New Jersey Ineligible Provider report (mandatory): https://nj.gov/comptroller/doc/nj_debarment_list.pdf
2. Federal exclusions database (mandatory): https://exclusions.oig.hhs.gov/
3. N.J. Treasurer's exclusions database (mandatory): http://www.state.nj.us/treasury/revenue/debarment/debarsearch.shtml
4. N.J. Division of Consumer Affairs licensure databases (mandatory): http://www.njconsumeraffairs.gov/Pages/verification.aspx
5. N.J. Department of Health licensure database (mandatory):http://www.state.nj.us/health/guide/find-select-provider/
6. Federal exclusions and licensure database (optional and fee-based): https://www.npdb.hrsa.gov/hcorg/pds.jsp
7. If the provider is out of state, you must also check that state's exclusion/debarment list

SELF-DISCLOSURE

- Providers who find problems within their own organizations, must reveal those issues to MFD and return inappropriate payments. https://nj.gov/comptroller/resources/#collapseSub30/

- Affordable Care Act §6402 and N.J.A.C. §10:49-1.5 (b)(1), (7)
  - require that any overpayments from Medicaid and/or Medicare must be returned within 60 days of identifying that they have been improperly received.

- Providers who follow the protocols for a proper self-disclosure can avoid imposition of penalties.

- MFD's Self Disclosure Form: https://nj.gov/comptroller/news/docs/self_disclosure_form.pdf

THIRD-PARTY LIABILITY (TPL)

- Third-Party Liability exists when any entity or party is or may be liable to pay all or part of the cost of medical assistance payable by the Medicaid program.
  - Examples: Medicare, commercial health insurance, Tricare
- By law, Medicaid is the payer of last resort. All TPL shall, if available, be used first and to the fullest extent to pay claims before Medicaid/NJ FamilyCare pays for the care of the Medicaid recipient.
- It is a violation of Section 1902(a)(25)(D) of the Federal Social Security Act to refuse to furnish covered services to any Medicaid beneficiary because of a third party's potential liability to pay for services (N.J.A.C. 10:49-7.3).

Name	Contact Information
TPL Hotline	(609) 826-4702
TPL Hotline en Español	(609) 777-2753

WRAP UP

FEE FOR SERVICE (FFS) CONTACTS

Name	Contact Number
FFS Provider Services	(800) 776-6334
FFS Pharmacy Prior Authorizations	(877) 888-2939

MCO PHARMACY HELP DESK CONTACTS

Name	Pharmacy Help Desk Contact Number
Aetna Better Health of New Jersey	(855) 232-3596
Fidelis Care	(888) 453-2534
Horizon NJ Health	(800) 682-9094
UnitedHealthcare Community Plan – OptumRx	(877) 305-8952
Wellpoint	(833) 207-3115

FRAUD, WASTE, AND ABUSE REPORTING

Name	Contact Number	FWA Reporting Website
Aetna Better Health of New Jersey	(855) 282-8272	Aetna FWA Reporting
Fidelis Care	(866) 685-8664	Fidelis Care FWA Reporting
Horizon NJ Health	(855)-372-8320	HNJH FWA Reporting
UnitedHealthcare Community Plan	(844) 359-7736	UHC FWA Reporting
Wellpoint	(866) 847-8247	Wellpoint FWA Reporting
NJ Office of the State Comptroller, Medicaid Fraud Division	(888) 937-2835	MFD FWA Reporting
NJ Medicaid Fraud Control Unit	(609) 292-1272	NJMFCU@njdcj.org

QUESTIONS? PLEASE CONTACT US!

- Board of Pharmacy
  - Email: NJBOPOffice@dca.njoag.gov
- Medicaid Fraud Division (MFD)
  - Email: provider-education@osc.nj.gov
  - Website: https://nj.gov/comptroller/about/work/medicaid/
- Medicaid Fraud Control Unit (MFCU)
  - Email: NJMFCU@njdcj.org
  - Website: https://www.njoag.gov/about/divisions-and-offices/office-of-the-insurance-fraud-prosecutor-home/medicaid-fraud-control-unit/

QUESTIONS?

Any questions we are unable to answer today, please submit in writing to:

provider-education@osc.nj.gov

HOW DID WE DO?

Please respond to a brief poll to help us know how we did!

KEEP IN TOUCH

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