

The Indiana Board of Pharmacy: Diversion and the Disciplinary Process



2012 DEA Pharmacy Diversion
Awareness Conference

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Director, Indiana Board of Pharmacy

Learning Objectives

- ▶ Indiana Board of Pharmacy background information
 - ▶ Rulemaking and diversion
 - ▶ Compliance and diversion
 - ▶ Licensing and diversion, particularly with respect to the disciplinary process
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The Indiana Board of Pharmacy

IC 25-26-13-1: “The practice of pharmacy is declared to be a professional occupation in the state of Indiana, affecting the **public health, safety, and welfare** and must be subject to regulation and control in the public interest by the board of pharmacy. It is further declared to be a matter of public interest and concern that the practice of pharmacy merit and receive the confidence of the public and that **only qualified persons be permitted to practice pharmacy** in the state of Indiana.”



Composition of the Board

- ▶ 7 members (6 Pharmacists and 1 Consumer Member)
 - 3 Retail Pharmacists
 - Bill Cover (*Goshen, Indiana*)
 - Del Fanning (*Vincennes, Indiana*)
 - Winnie Landis (*Lafayette, Indiana*)
 - 2 Hospital Pharmacists
 - Sara St. Angelo (*Indianapolis, Indiana*)
 - Donna Wall (*Indianapolis, Indiana*)
 - 1 Independent Pharmacist
 - Steve Anderson (*Bedford, Indiana*)
 - 1 Consumer Member
 - Lora Williams, Esq. (*Greensburg, Indiana*)
- ▶ Political Split (Required by Statute)
 - NO more than four members from any one political party

Board of Pharmacy Core Functions

- ▶ Administrative Rulemaking
- ▶ Compliance
- ▶ Licensing & Discipline
- ▶ INSPECT



Administrative Rulemaking



Administrative Rulemaking

- ▶ Authority to promulgate rules: Indiana Code 25-26-13-4
- ▶ Title 856 of the Indiana Administrative Code

Prescription Drug Take Back

- ▶ IC 25–26–23. Returning Unused Medications
- ▶ 856 IAC 7. Prescription Drug Take Back Programs
- ▶ “Take back program” refers to a program or service intended to collect unused or unwanted medication from consumers or patients, and established and run under the guidelines and standards as laid out in this article.”
- ▶ Secure and Responsible Drug Disposal Act passed in September 2010

Prescription Drug Take Back

- ▶ Establishes definitions
 - ▶ Provides immunity from liability
 - ▶ Lays out personnel requirements
 - ▶ Establishes destruction requirements and protocols
 - ▶ Prohibition on reuse, redistribution, and resale
 - ▶ Privacy issues & consumer notices
 - ▶ Third party vendors, transportation, and security
 - ▶ Access to contents in receptacles
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Prescription Drug Take Back

- ▶ What does it NOT do?
 - It does not end existing Take Back Programs offered by local solid waste programs
 - It does not end existing Take Back Programs offered by federal, state, or local law enforcement agencies
 - It does not require entities to participate in Take Back Programs
 - It does not require a mandate on law enforcement participation
 - It does not require a fee or charge

Compliance



Board of Pharmacy Staff: Compliance

Compliance Director: Deborah Frye

Compliance Officers:

Central: Zaneta Nunnally

Central Northeast: Tim Thomas

Central Northwest: Lorena Sipe

Southeast: Eric Pearcy

Southwest: Amy Phillips

North: Vacant



Compliance: Inspections

▶ Opening Inspections

- *IC 25-26-13-18*
Eligibility for pharmacy permits; inspections; value of drug inventory

▶ Closing Inspections

- *IC 25-26-13-27*
Closing of pharmacies
... (3) before disposing of any other merchandise in the pharmacy, dispose of all controlled drugs and legend drugs as provided in clauses (1) and (2) and submit the licensed premises to an inspection by a representative of the board to certify that all legend and controlled drugs have been removed;

▶ Remodel Inspections

▶ Quality Assurance Inspections

- *IC 25-26-13-25*
Prescriptions; numbering, filing, and inspection; refills; duration of validity; demise of practitioner or patient; resale or redistribution of returned medication
- *IC 25-26-13-4*
Powers and duties of board; prescription drug form program
- *IC 16-42-20*
Chapter 20. Drugs: Enforcement of Pharmacy Laws and Rules

Compliance: Corrective Action and Remediation

- ▶ What do we do? What can we do?
 - We have the authority to issue violations, close pharmacies, confiscate and impound dangerous drugs and product, file complaints with the Attorney General's Office, work with law enforcement, obtain warrants, and act as law enforcement officers.
- ▶ What do we expect – what do we prefer to do?
 - Our mission is to serve the public and protect consumers, and it is our belief that the best way to do this is to monitor for and help licensees achieve compliance with the laws and regulations set down by the Board and Legislature.

Compliance: Reporting Loss and Theft

- ▶ 856 IAC 2-3-35(b): “The registrant shall notify the Indiana Board of Pharmacy of the theft or significant loss of any controlled substances upon discovery of such loss or theft.”

Compliance: Prescription Pads

- ▶ Security feature requirements for controlled substance prescriptions
- ▶ 856 IAC 1-34



Practice LOGO 1 inch Practitioner Name
State Issued Professional License Number

1 inch

Name: _____
Address: _____ Date: _____

Refill NR 1 2 3 4 5 Void after: _____

1-24
 25-49
 50-74
 75-100
 101-150
 151 and over

Dispense as Written May Substitute

Prescription is void if more than one (1) prescription is written per blank.



INDIANA SECURITY FEATURES FOR PRESCRIPTIONS

All controlled substance prescriptions written by licensed Indiana practitioners, as defined by IC 16-42-19-5, must contain the following security features:

VOID PATTERN

(1) A latent, repetitive "Void" pattern screened at five percent (5%) in reflex blue must appear across the entire face of the document when the prescription is photocopied.

WATERMARK ON BACKSIDE

(2) There shall be a custom artificial watermark printed on the back side of the base paper so that it may only be seen at a forty-five (45) degree angle. The watermark shall consist of the words "Indiana Security Prescription", appearing horizontally in a step-and-repeated format in five (5) lines on the back of the document using 12-point Helvetica bold type style.

RX SYMBOL

(3) An opaque RX symbol must appear in the upper right-hand corner, one-eighth (1/8) of an inch from the top of the pad and five-sixteenths (5/16) of an inch from the right side of the pad. The symbol must be three-fourths (3/4) inch in size and must disappear if the prescription copy is lightened.

CHECK BOXES

(4) Six (6) quantity check-off boxes must be printed on the form and the following quantities must appear and the appropriate box be checked off for the prescription to be valid:

- (A) 1-24
- (B) 25-49
- (C) 50-74
- (D) 75-100
- (E) 101-150
- (F) 151 and over

NO ADVERTISEMENTS

(5) No advertisements may appear on the front or back of the prescription blank.

ONE INCH SQUARE FOR LOGOS

(6) Logos, defined as a symbol utilized by an individual, professional practice, professional association, or hospital, may appear on the prescription blank. The upper left one (1) inch square of the prescription blank is reserved for the purpose of logos. Only logos, as defined by this subdivision, may appear on the prescription blank.

ONE PRESCRIPTION PER BLANK

(7) Only one (1) prescription may be written per prescription blank. The following statement must be printed on the bottom of the pad: "Prescription is void if more than one (1) prescription is written per blank."

REFILL OPTIONS

(8) Refill options that can be circled by the prescriber must appear below any logos and above the signature lines on the left side of the prescription blank in the following order:

Refill NR 1 2 3 4 5 Void after _____

NAME AND LICENSE NUMBER

(9) Practitioner name and state issued professional license number must be preprinted, stamped, or manually printed on the prescription.

SIZE OF PRESCRIPTION BLANK

(10) All prescription blanks printed under this rule shall be four and one-fourth (4 1/4) inches high and five and one-half (5 1/2) inches wide.

Licensing and Discipline



Board of Pharmacy Staff: Licensing

Assistant Director: Amy Hall

Case Managers:

Rejina Henderson Stigger

Deborah Mattingly Huber

Anita Lovejoy

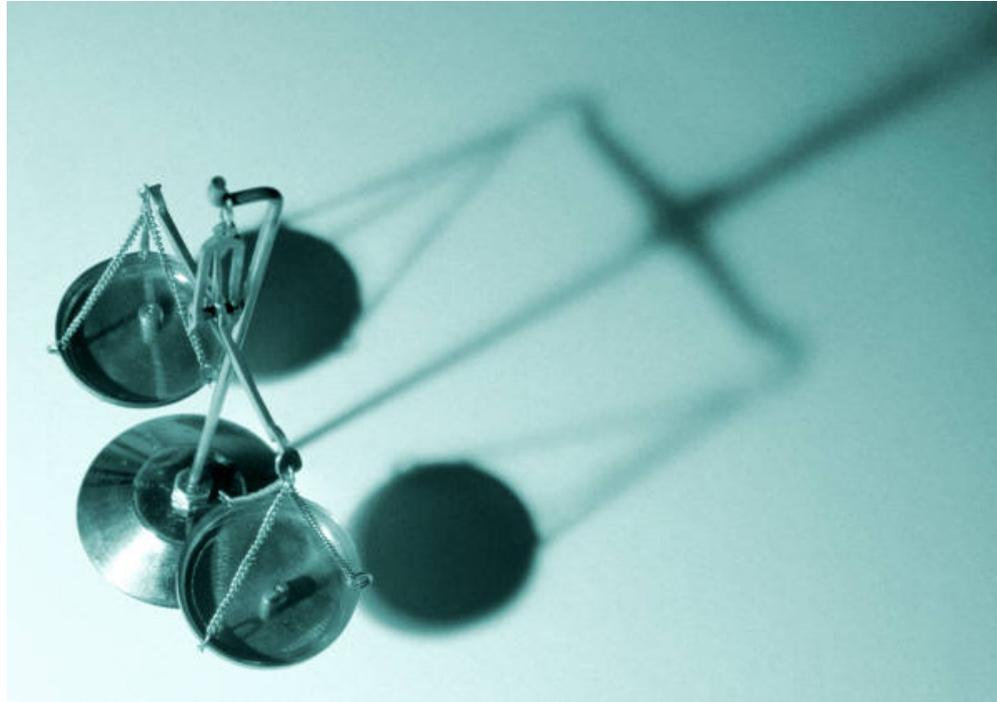
Litigation Specialist: Jacqueline Day



Licensing

- ▶ **Criminal Background Checks**
 - Effective July 1, 2011
 - Initial Pharmacist, Pharmacy Technician, and Pharmacy Technician–In–Training applications require national criminal history background checks.
- ▶ **Pharmacy Technician Qualifications**
 - Effective July 1, 2012
 - IC 25–26–19–5(a)(3)(B): ...”has not been convicted of: ... (B) a felony involving controlled substances.”

The Disciplinary Process



The Disciplinary Process

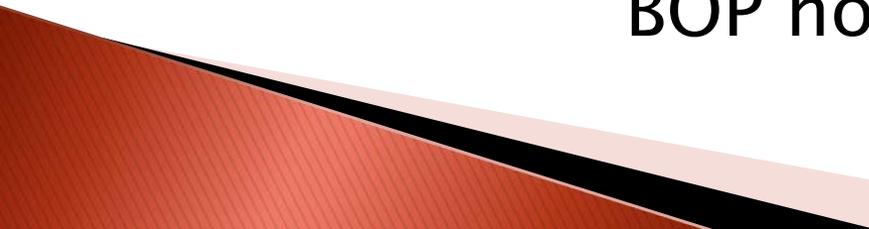
Consumer complaint is filed

OAG Investigates

OAG files for summary suspension or
administrative complaint

BOP sends hearing notice

BOP holds a hearing



The Disciplinary Process

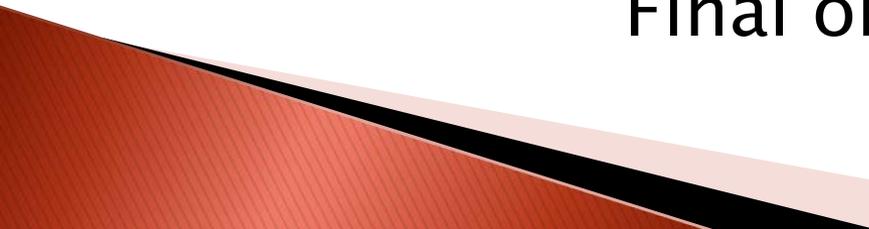
BOP holds a hearing

Respondent appears and hearing is held

Or

Respondent does not appear and BOP issues
notice of proposed default

Final order is issued



The Disciplinary Process

Final Order

Dismiss

Suspension

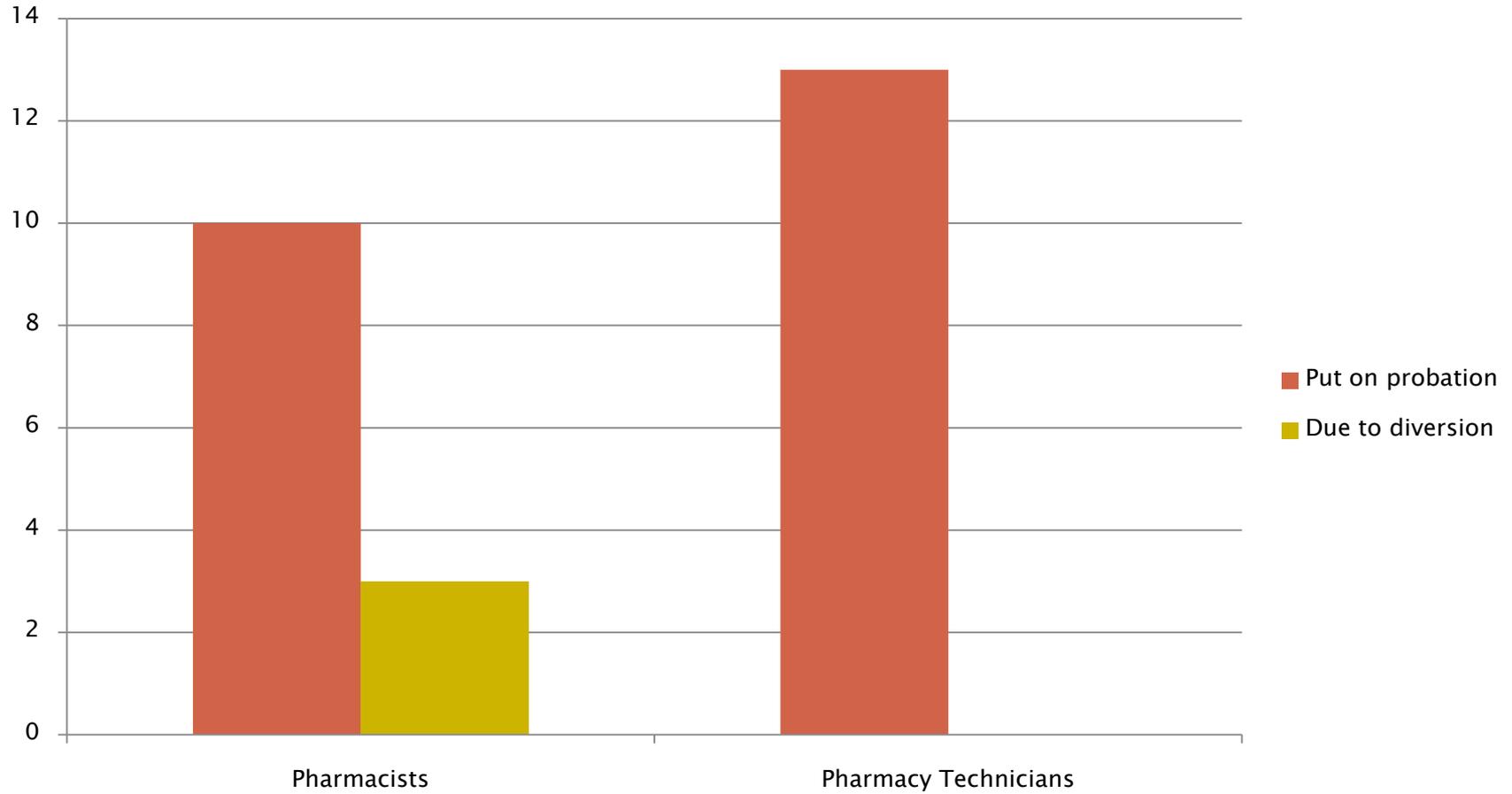
Revocation

Probation

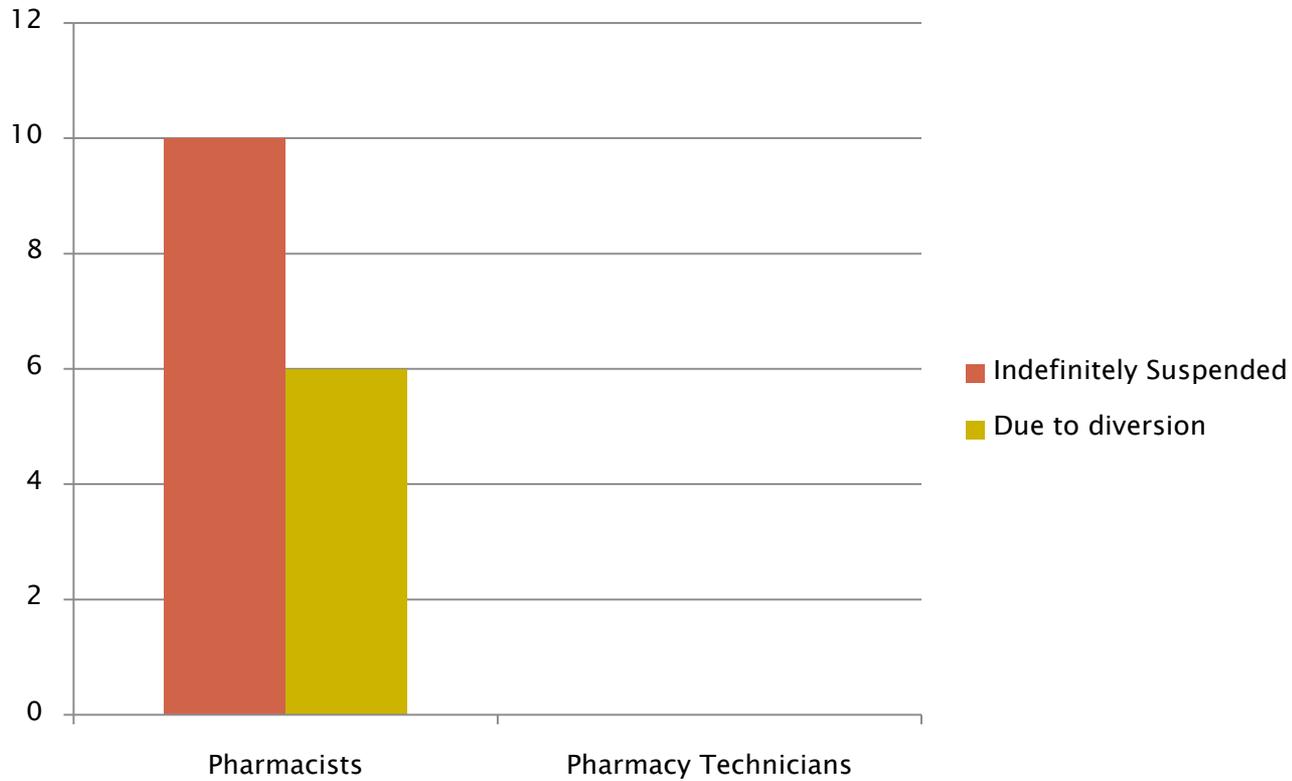
Accept proposed settlement agreement



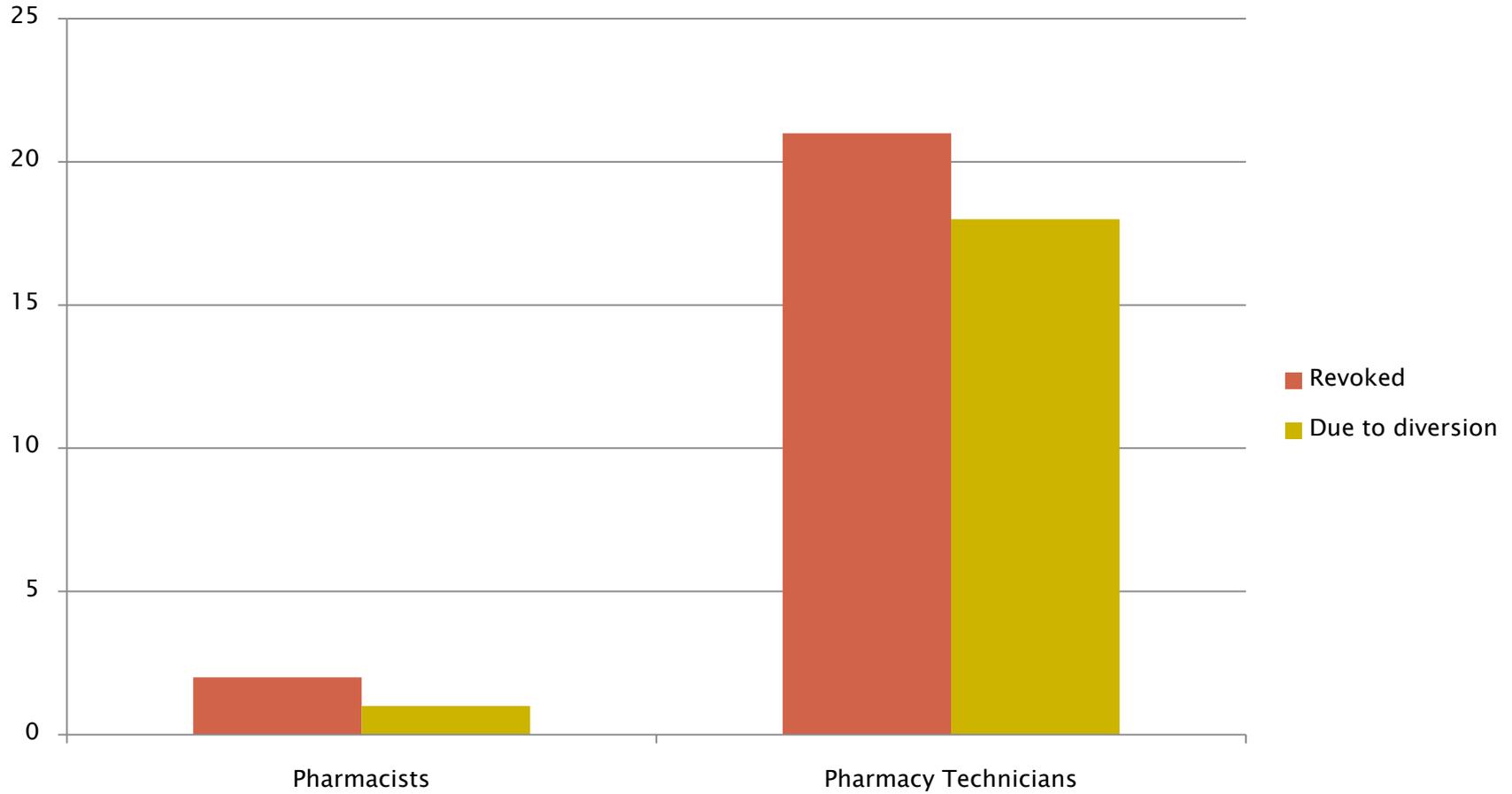
Probation: 2012



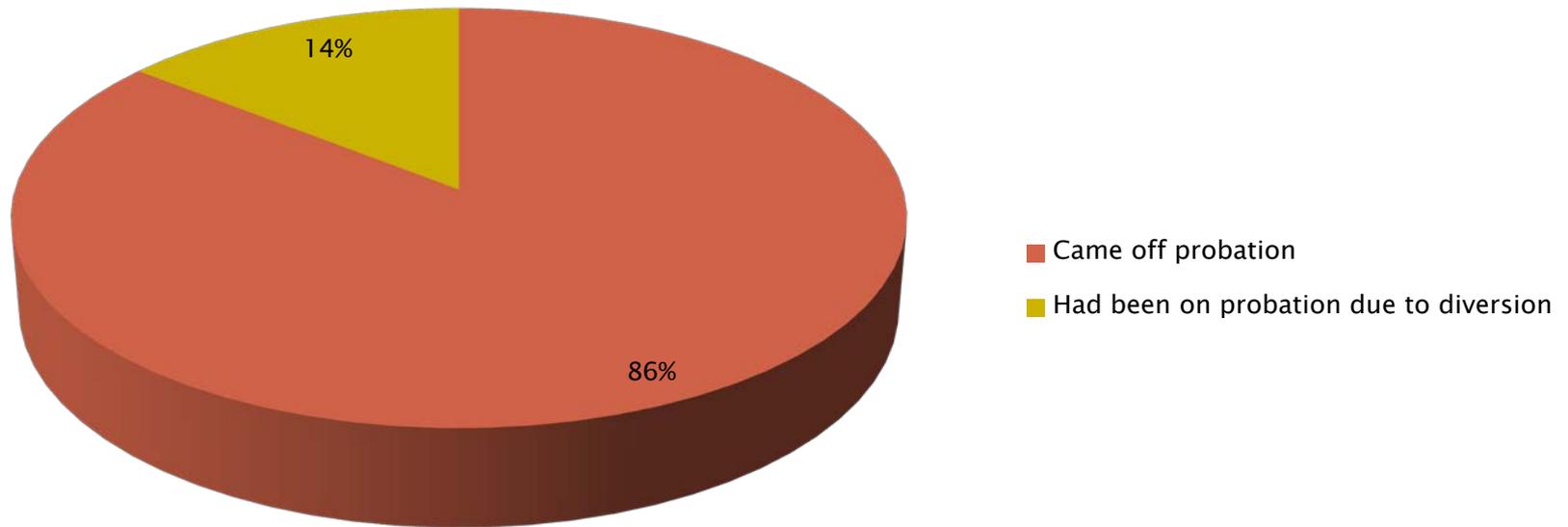
Suspensions: 2012



Revocations: 2012



Probationary Licenses Reinstated in 2012



Indiana Pharmacists Recovery Network

- ▶ www.prnindiana.com
- ▶ 877-624-4401 or 317-624-4401
- ▶ Confidentiality: IC 25-26-13-4.5

Contact Information

- ▶ www.bop.in.gov
- ▶ 317-234-2067
- ▶ pla4@pla.in.gov

