APPENDIX D

BOARD OF PHARMACY
State of North Dakota

Jack Dalrymple, Governor

OFFICE OF THE EXECUTIVE DIRECTOR
1906 E Broadway Ave
Bismarck, ND 58501-4700
Telephone (701) 328-9535
Fax (701) 328-9536

www.nodakpharmacy.com
ndboph@btinet.net

Mark J. Hardy, PharmD, R.Ph.
Assistant Executive Director
Howard C. Anderson, Jr, R.Ph.
Executive Director

Chairman Kaiser and Members of the Health Care Reform Review Committee:

For the record my name is Mark Hardy, Assistant Executive Director of the North Dakota Board of Pharmacy. I am going to give you the background on the ND Prescription Drug Monitoring Program (PDMP), detail the current legislation and rules regarding the PDMP, and give you some facts and figures regarding the PDMP.

The 2005 North Dakota Legislative Assembly authorized the implementation of a Prescription Drug Monitoring Program. The purpose of this program is to collect data on all Schedule II, III, IV, and V controlled substances, including tramadol, dispensed in the state of North Dakota or for patients residing in North Dakota. In 2007, Senate Bill 2134 created the current language into law and placed the program under the Board of Pharmacy. The laws and rules regarding the PDMP are included.

The PDMP was started with the assistance of a Bureau of Justice Assistance Harold Rodgers implementation grant which funded the program for the first 2 years. We received enhancement grants which allowed us to do research plus program education and training. Since October 2009, the program is been funded through the reserves of the Board of Pharmacy. Moving forward, we plan on bringing legislation to the next session to implement a Controlled Substance Registration, which we will ask to be the long term funding mechanism for the PDMP. A Controlled Substance Registration will also serve as an additional tool to monitor who can receive and where controlled substances are handled in the state.

Each dispenser is required to submit their dispensing history for controlled substances and tramadol to our contracted vendor Health Information Design (HID). Our state is unique in that it requires daily reporting to the PDMP compared to a weekly reporting for most other states. We feel the daily reporting is important to give a user the most up to date information to ensure best patient care.

The legislation contains a list of individuals that you have granted access to the information in the database. I will briefly go thru them with you.

Prescribers and pharmacists, along with having their own login for direct access, can assign delegates to access the program under their authority. We feel this is important to incorporating the PDMP in the workflow of the practitioner and pharmacist.

We also have an advisory council to comply with NDCC 19-03.5-07. They provide us with insight and recommendations on how to improve our program. They also provide a forum for the interdisciplinary approach to continue to tackle the current trends we are seeing. I provided an updated handout of the facts and figures that we provide to them and I will go through this with you so you can get a better understanding of the PDMP.

We strongly feel one of our ongoing responsibility is to increase the utilization of the program to ensure the best patient care is being administered. We continue to educate through the use of newsletters, mailings, and speaking to potential groups of users. We also have purchased numerous copies of a pain management education program through the American Medical Association for practitioners and pharmacists to get for free through NDSU. We are looking forward to teaming with the ND Board of Medical Examiners to do some presentations to practitioners in facilities about best practices around the state.

I would be happy to answer any questions that you may have.

Respectfully submitted,
Mark Hardy

CHAPTER 19-03.5
PRESCRIPTION DRUG MONITORING PROGRAM

19-03.5-01. Definitions.

1. "Board" means the state board of pharmacy.
2. "Central repository" means a place where electronic data related to the prescribing and dispensing of controlled substances is collected.
3. "Controlled substance" means a drug, substance, or immediate precursor defined in section 19-03.1-01 and nonscheduled substances containing tramadol or carisoprodol.
4. "De-identified information" means health information that is not individually identifiable information because an expert has made that determination under title 45, Code of Federal Regulations, section 164.514 or direct identifiers and specified demographic information have been removed in accordance with the requirements of that section.
5. "Dispense" means to deliver a controlled substance to an ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.
6. "Dispenser" means an individual who delivers a controlled substance to the ultimate user but does not include a licensed hospital pharmacy that provides a controlled substance for the purpose of inpatient hospital care or a licensed health care practitioner or other authorized individual in those instances when the practitioner administers a controlled substance to a patient.
7. "Individually identifiable health information" has the meaning set forth in title 45, Code of Federal Regulations, section 160.103.
8. "Patient" means an individual or the owner of an animal who is the ultimate user of a controlled substance for whom a prescription is issued or for whom a controlled substance is dispensed.
9. "Prescriber" means an individual licensed, registered, or otherwise authorized by the jurisdiction in which the individual is practicing to prescribe drugs in the course of professional practice.
10. "Program" means the prescription drug monitoring program implemented under this chapter.

19-03.5-02. Requirements for prescription drug monitoring program.

1. The board shall establish and maintain a program for the monitoring of prescribing and dispensing of all controlled substances.
2. Each dispenser shall submit to the board by electronic means information regarding 3.5each prescription dispensed for a controlled substance. The information submitted for each prescription must include all of the data elements in the American Society for Automation in Pharmacy Rules-Based Standard Implementation Guide for Prescription Monitoring Programs issued August 31, 2005, version 003, release 000.
3. Each dispenser shall submit the information in accordance with transmission methods and frequency established by the board.
4. The board may issue an extension of time to a dispenser that is unable to submit prescription information by electronic means.

19-03.5-03. Access to prescription information.

1. Information submitted to the central repository is confidential and may not be disclosed except as provided in this section.
2. The board shall maintain procedures to ensure that the privacy, confidentiality, and security of patient information collected, recorded, transmitted, and maintained is not disclosed except as provided in this section.
3. Unless disclosure is prohibited by law, the board may provide data in the central repository to:
   a. A prescriber for the purpose of providing medical care to a patient, a dispenser for the purpose of filling a prescription or providing pharmaceutical care for a patient, a prescriber or dispenser inquiring about the prescriber's or dispenser's own prescribing activity, or a prescriber or dispenser in order to further the purposes of the program;
   b. An individual who requests the prescription information of the individual or the individual's minor child;
   c. State boards and regulatory agencies that are responsible for the licensing of individuals authorized to prescribe or dispense controlled substances if the board or regulatory agency is seeking information from the central repository that is relevant to an investigation of an individual who holds a license issued by that board or regulatory agency;
   d. Local, state, and federal law enforcement or prosecutorial officials engaged in the enforcement of laws relating to controlled substances who seek information for the purpose of an investigation or prosecution of the drug-related activity or probation compliance of an individual;

e. The department of human services for purposes regarding the utilization of controlled substances by a medicaid recipient;
f. Workforce safety and insurance for purposes regarding the utilization of controlled substances by a claimant;
g. Judicial authorities under grand jury subpoena or court order or equivalent judicial process for investigation of criminal violations of controlled substances laws;
h. Public or private entities for statistical, research, or educational purposes after the information is de-identified with respect to any prescriber, dispenser, or patient who received a prescription for a controlled substance;
i. A peer review committee which means any committee of a health care organization, composed of health care providers, employees, administrators, consultants, agents, or members of the health care organization's governing body, which conducts professional peer review as defined in chapter 23-34; or
j. A licensed addiction counselor for the purpose of providing services for a licensed treatment program in this state.

4. The board shall maintain a record of each person who requests information from the central repository. The board may use the records to document and report statistics and outcomes. The board may provide records of the requests for information to:
   a. A board or regulatory agency responsible for the licensing of individuals authorized to prescribe or dispense controlled substances that is engaged in an investigation of the individual who submitted the request for information from the central repository; and
   b. Local, state, and federal law enforcement or prosecutorial officials engaged in the enforcement of laws relating to controlled substances for the purpose of an active investigation of an individual who requested information from the central repository.

19-03.5-04. Authority to contract.

The board is authorized to contract with another agency of this state or with a private vendor to facilitate the effective operation of the prescription drug monitoring program. Any contractor is bound to comply with the provisions regarding confidentiality of prescription drug information in this chapter and is subject to termination or sanction or both for unlawful acts.

19-03.5-05. Immunity.

Nothing in this chapter requires a prescriber or dispenser to obtain information about a patient from the central repository prior to prescribing or dispensing a controlled substance. A prescriber, dispenser, or other health care practitioner may not be held liable in damages to any person in any civil action on the basis that the prescriber, dispenser, or other health care practitioner did or did not seek to obtain information from the central repository. Unless there is shown a lack of good faith, the board, any other state agency, a prescriber, dispenser, or any other individual in proper possession of information provided under this chapter may not be subject to any civil liability by reason of:

1. The furnishing of information under the conditions provided in this chapter;
2. The receipt and use of, or reliance on, such information;
3. The fact that any such information was not furnished; or
4. The fact that such information was factually incorrect or was released by the board to the wrong person or entity.

19-03.5-06. Data review and referral - Corrections.

1. a. The board shall review the information received by the central repository to determine if there is reason to believe:
      (1) A prescriber or dispenser may have engaged in an activity that may be a basis for disciplinary action by the board or regulatory agency responsible for the licensing of the prescriber or dispenser; or
      (2) A patient may have misused, abused, or diverted a controlled substance.
   b. If the board determines that there is reason to believe that any of the acts described in subdivision a may have occurred, the board may notify the appropriate law enforcement agency or the board or regulatory agency responsible for the licensing of the prescriber or dispenser. The advisory council described in section 19-03.5-07 shall recommend guidelines to the board for reviewing data and making determinations with respect to the referral of patients, prescribers, or dispensers to law enforcement or appropriate regulatory authorities.
2. A patient, dispenser, or prescriber may request that erroneous information contained in the central repository be corrected or deleted. The board shall review the request to determine if the information is erroneous with respect to the patient, prescriber, or dispenser. The board shall

correct any erroneous information the board discovers due to the request for review by a patient, prescriber, or dispenser.

3. The board shall adopt a procedure to allow information contained in the central repository to be shared with officials in other states acting for the purpose of controlled substance monitoring and for requesting and receiving similar controlled substance monitoring information from other states.

19-03.5-07. Advisory council.

1. An advisory council is established to advise and make recommendations to the board regarding how to best use the program to improve patient care and foster the goal of reducing misuse, abuse, and diversion of controlled substances; to encourage cooperation and coordination among state, local, and federal agencies and other states to reduce the misuse, abuse, and diversion of controlled substances; and to provide advice and recommendations to the board regarding any other matters as requested by the board. The advisory council may have access to central repository information to fulfill its duties.
2. The advisory council must consist of:
   a. One dispenser selected by the board;
   b. One physician selected by the North Dakota medical association;
   c. One prescriber selected by the board of nursing;
   d. A designee of the attorney general;
   e. A designee of the department of human services;
   f. One prescriber selected by the board of medical examiners;
   g. One prescriber selected by the North Dakota nurses association; and
   h. Any other prescriber or dispenser determined by the board to be necessary to meet a mandate of, or avoid a delay in implementing, an appropriations measure.

   The number of additional members selected by the board must be limited to the number necessary to meet the mandate or avoid the delay of an appropriation.
3. The advisory council shall make recommendations to the board regarding:
   a. Safeguards for the release of information to individuals who have access to the information contained in the central repository;
   b. The confidentiality of program information and the integrity of the patient's relationship with the patient's health care provider;
   c. Advancing the purposes of the program, including enhancement of the quality of health care delivery in this state; and
   d. The continued benefits of maintaining the program in relationship to the cost and other burdens to the state.
4. The board may provide reimbursement of expenses and per diem to members of the advisory council within the limits provided in state law.

19-03.5-08. Extraterritorial application.

The board may provide data in the central repository to a practitioner or controlled substances monitoring system in another state, if the disclosure to a practitioner or the prescription drug monitoring program located in this state is authorized by this chapter.

19-03.5-09. Authority to adopt rules.

The board may adopt rules that set forth the procedures and methods for implementing this chapter.

19-03.5-10. Reporting unlawful acts and penalties.

1. The board may report to a dispenser's licensing board any dispenser who knowingly fails to submit prescription drug monitoring information to the board as required by this chapter or who knowingly submits incorrect prescription information to the board.
2. A person, including a vendor, who uses or discloses prescription drug monitoring information in violation of this chapter is subject to the penalty provided in section 12.1-13-01.

Article 61-12

PRESCRIPTION DRUG MONITORING PROGRAM

Chapter 61-12-01
PRESCRIPTION DRUG MONITORING PROGRAM

61-12-01-01. Definitions. For purposes of this chapter:

1. "Board" means the North Dakota board of pharmacy.

2. "Central repository" means a place where electronic data related to the prescribing and dispensing of controlled substances is collected.

3. "Controlled substance" means a drug, substance, or immediate precursor in schedules I through V as set out in North Dakota Century Code chapter 19-03.1 and any other drugs required by law to be monitored by the program.

4. "De-identified information" means health information that is not individually identifiable information because an expert has made that determination under title 45, Code of Federal Regulations, section 164.514, or direct identifiers and specified demographic information have been removed in accordance with the requirements of that section.

5. "Department" means the North Dakota department of human services.

6. "Dispense" means to deliver a controlled substance to an ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

7. "Dispenser" means an individual who delivers a controlled substance to the ultimate user, but does not include:

   a. A licensed hospital pharmacy that provides a controlled substance for the purpose of inpatient hospital care; or

   b. A licensed health care practitioner or other authorized individual in those instances when the practitioner administers a controlled substance to a patient. For purposes of this section, administer means the direct application of a controlled substance to the body of a patient and does not include the prescribing of a controlled

substance for administration by the patient or someone other than the health care practitioner.

8. "Individually identifiable health information" has the meaning set forth in title 45, Code of Federal Regulations, section 160.103.

9. "Patient" means an individual or the owner of an animal who is the ultimate user of a controlled substance for whom a prescription is issued and for whom a controlled substance is dispensed.

10. "Prescriber" means an individual licensed, registered, or otherwise authorized by the jurisdiction in which the individual is practicing to prescribe drugs in the course of professional practice.

11. "Program" means the North Dakota prescription drug monitoring program implemented under NDCC chapter 19-03.5.

History: Effective December 1, 2006.
General Authority: NDCC 19-03.5
Law Implemented: NDCC 19-03.5

61-12-01-02. Dispenser Reporting.

1. Each dispenser licensed by a regulatory agency in the state of North Dakota who dispenses a controlled substance to a patient shall submit to the central repository by electronic means information regarding each prescription dispensed for a controlled substance. The information submitted for each prescription shall include all of the data elements in the American society for automation in pharmacy rules-based standard implementation guide for prescription monitoring programs issued August 31, 2005, version 003, release 000.

2. Each dispenser shall submit the information required by this chapter to the central repository at least once every day unless the board waives this requirement for good cause shown by the dispenser.

3. An extension of the time in which a dispenser must report the information required by this chapter may be granted to a dispenser that is unable to submit prescription information by electronic means if:

   a. The dispenser suffers a mechanical or electronic failure or cannot report within the required time for other reasons beyond the dispenser's control; or

   b. The central repository is unable to receive electronic submissions.

History: Effective December 1, 2006.
General Authority: NDCC 19-03.5

Law Implemented: NDCC 19-03.5

61-12-01-03. Operation of program.

1. The board may charge a fee to an individual who requests the individual's own information from the central repository.

2. The board may charge a fee to a person who requests statistical, aggregate, or other de-identified information.

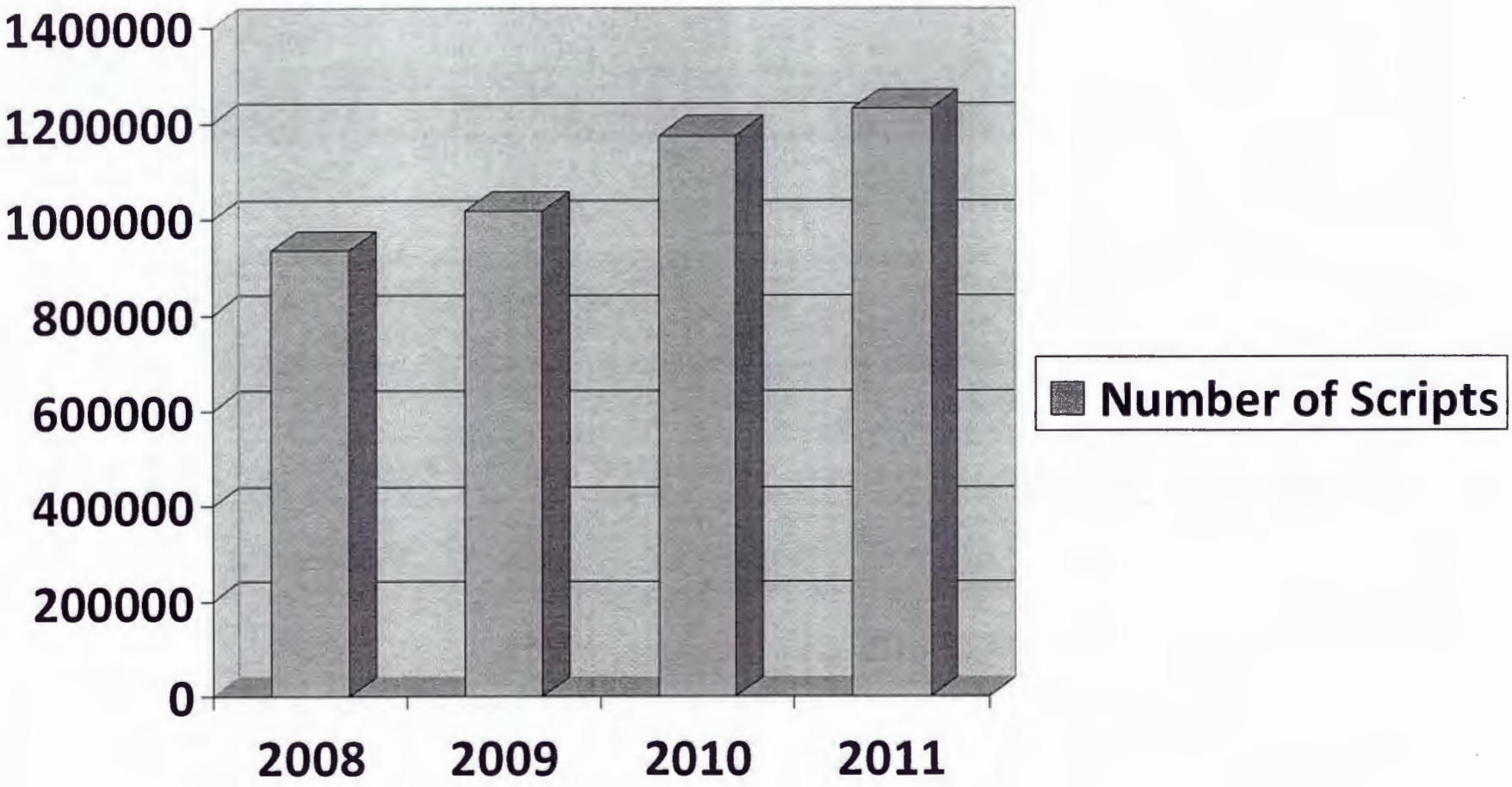
History: Effective December 1, 2006.
General Authority: NDCC 19-03.5
Law Implemented: NDCC 19-03.5

North Dakota Board of Pharmacy

Prescription Drug Monitoring Program

Facts & Figures

Prescriptions for North Dakota Residents submitted to the PDMP



Program Utilization

Prescribers

- **743** ND prescribers requested a patient profile report from March 2011 last year, from a total of 2970 ND prescribers that prescribed to patients during that same time period.
- **25%** of prescribers utilizing the NDPDMP in the past year. (*Previous Utilization Rate: 25.5% reported in Nov. 2011, 26.7% July)*

Dispenser

- **221** pharmacists (from a total of 795 licensed instate pharmacists) requested a patient profile since Feb 2011.
- **27.8%** of all licensed in-state pharmacists utilized this program in the past year. (*Previous Utilization Rate: 25.8% reported in Nov. 2011, 22.3% reported in July 2011) 3.5% increase in 4 months.*

Law Enforcement

- **97** ND Law enforcement officers requested a patient profile in the past year.

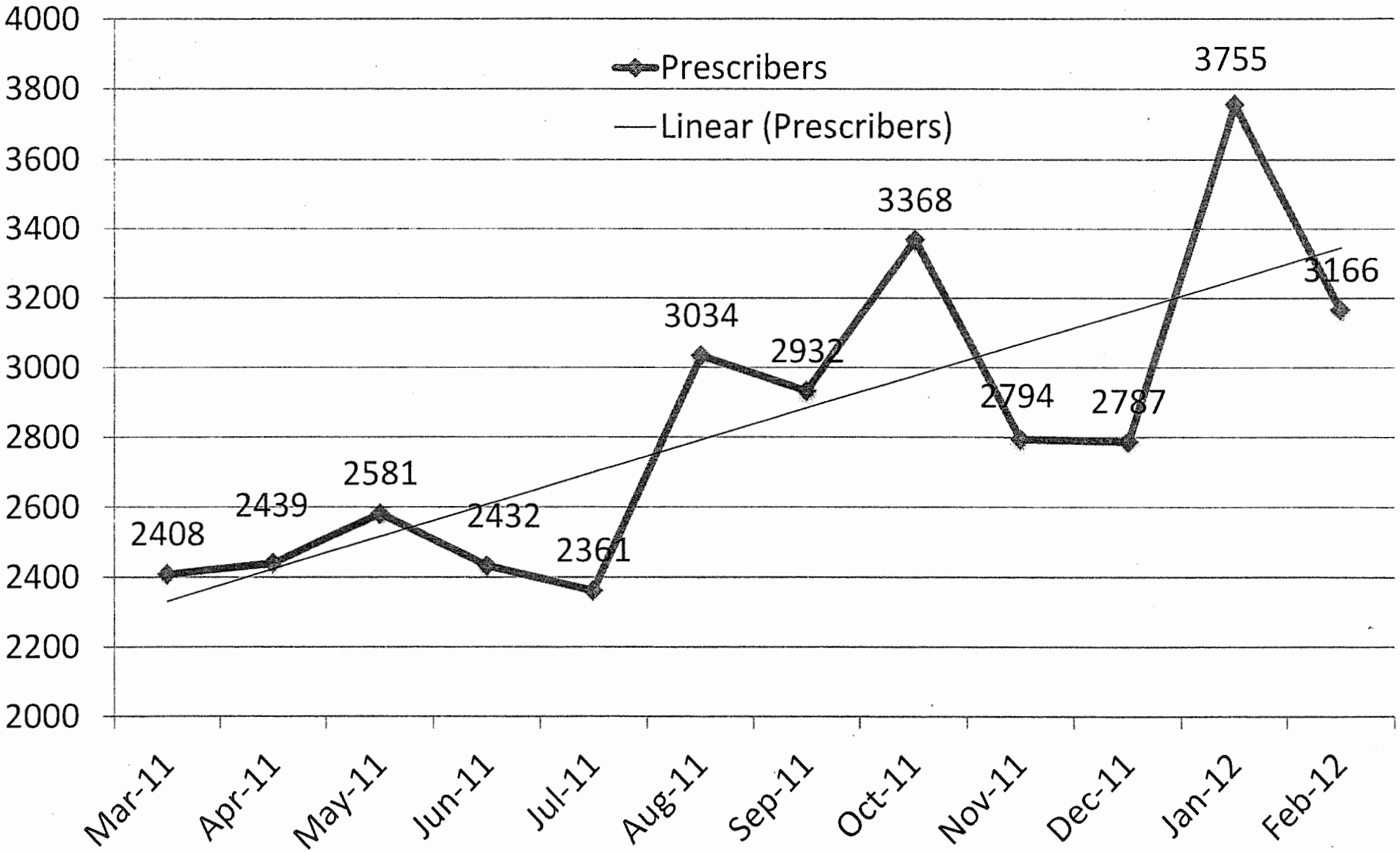
Licensed Addiction Counselors

- **48** ND Licensed Addiction Counselors in a state licensed facility have requested a patient profile in the past year.

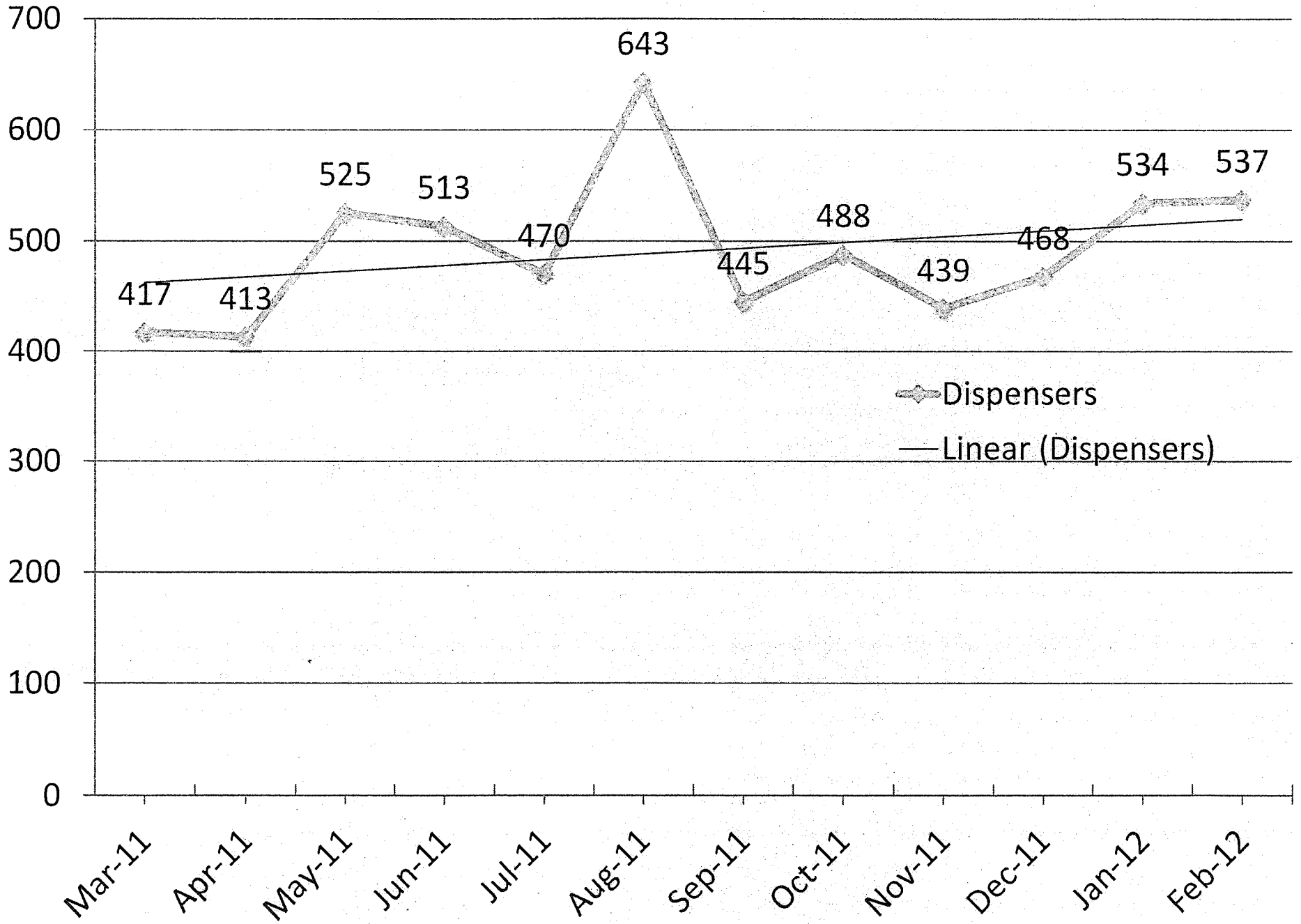
Other

- **22** other authorized users

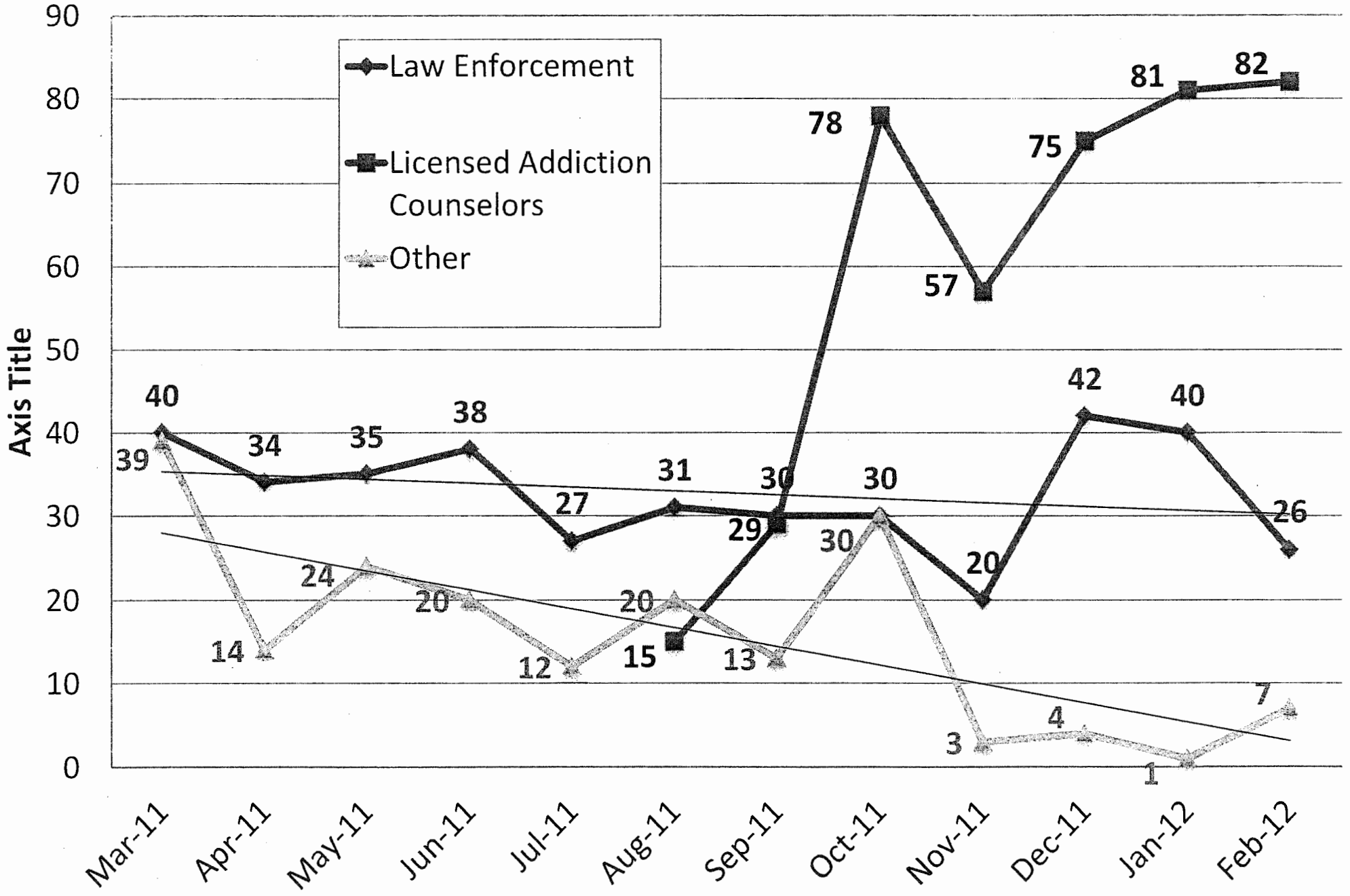
Monthly Queries by Group



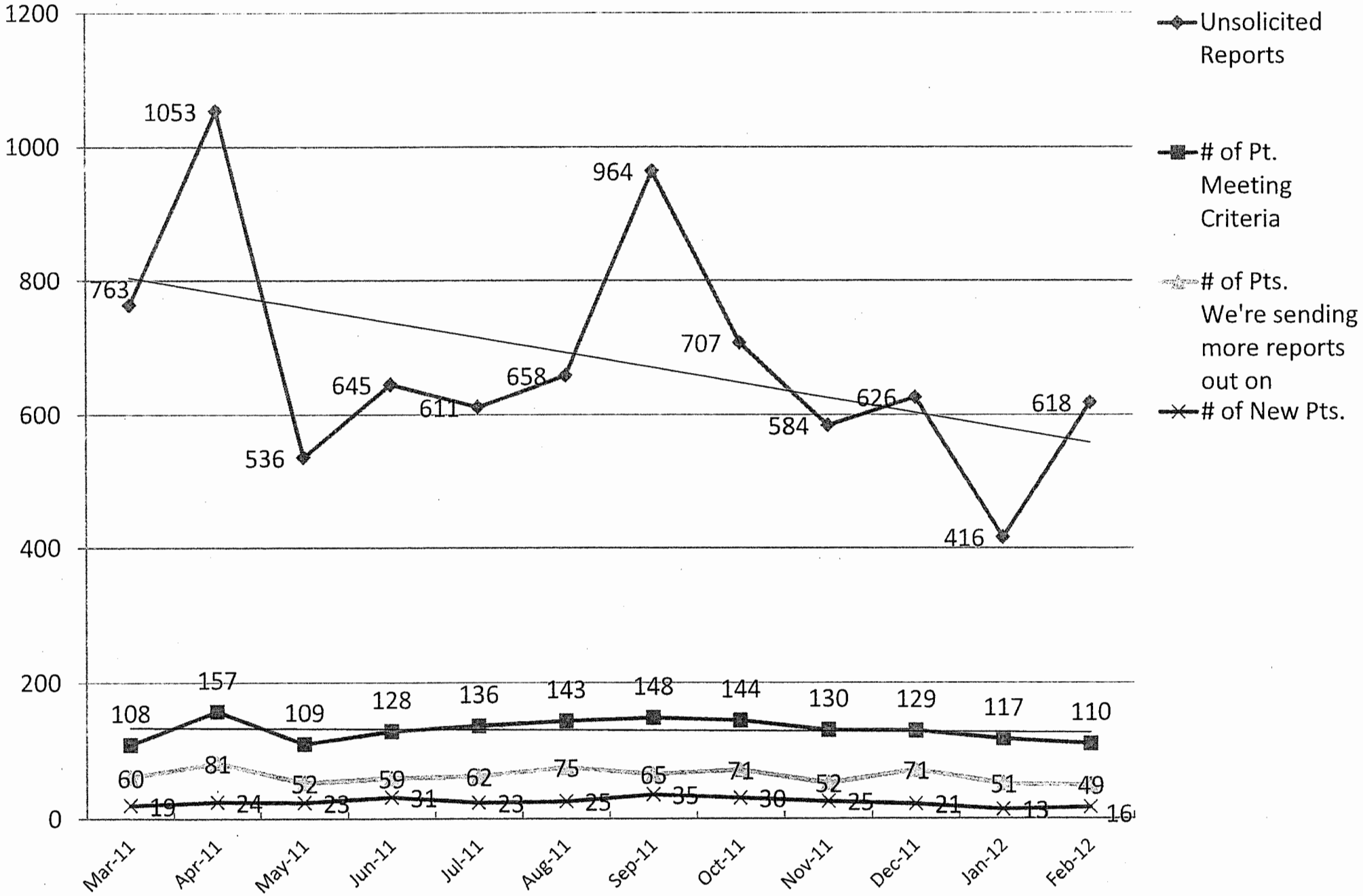
Monthly Queries by Group



Monthly Queries by Group



Unsolicited Reports



Fax and Online Requests By:	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11	Oct-11	Nov-11	Dec-11	Jan-12	Feb-12	Total	%
Law Enforcement	40	34	35	38	27	31	30	30	20	42	40	26	393	1%
Licensed Addiction Counselors	-	-	-	-	-	15	29	78	57	75	81	82	417	1.03%
Others	12	5	8	12	10	6	4	9	3	4	1	7	81	0.2%
Dispensers	417	413	525	513	470	643	445	488	439	468	534	537	5892	14.6%
Prescribers	2114	2439	2581	2432	2361	3034	2932	3368	2794	2787	3755	3166	33763	83.4%
Grand Totals	2495	2891	3149	2995	2868	3729	3440	3973	3341	3385	4405	3802	40561	--
Indian Health Services	155	240	251	206	237	231	143	156	146	151	300	113	2329	5.8%

Online Requestor Details

- A total of 1057 Individuals have direct access to the database. With 272 applicants waiting to be processed.

Of those:

- 246 are Pharmacy related accounts (Nov. 2011, 226 reported)
  - 224 Pharmacists and 22 Delegates
- 763 are Prescriber related accounts (Nov. 2011, 660 reported)
  - 536 Practitioners and 227 Delegates
- 48 are License Addiction Counselor accounts (Nov. 2011, 33 reported)
- From Mar. 2011 – Feb. 2012 online accounts were responsible for generating 40,473 reports. (up from 34,388/one year)

Direct Access Account Totals