# Comprehensive Analysis of Electronic Prescribing Quality Related-Incidents

Select a Project/Research Category

- ❑ Patient
- ❑ Survey
- ❑ **X Other**

## I. Background

The purpose of this study is to improve electronic (e) prescribing medication safety. E-prescribing adoption has been increasingly encouraged by national and federal organizations as a means to improve patient safety. Consequently, last year, over 1.2 billion of prescriptions were submitted electronically in the United States (US).[1] At the same time, there is a growing awareness that e-prescribing can introduce errors. Community pharmacists are on the receiving end of the e-prescribing transactions. Yet, the study of e-prescribing impact on facilitating incident and errors, that affect community pharmacist and patients, is in its infancy.[2] Recent studies have characterized e-prescribing errors that were detected in community pharmacies by using observation[3], other qualitative methods[4,5] and limited quantitative data.[6-8] To date, robust analyses of e-prescribing errors have occurred amidst of hospital settings or industry sponsored initiatives but not in community pharmacy.[9]

An increasing number of national stakeholders, such as Surescripts, have delineated software recommendations for e-prescription orders. Yet, it is unknown the extent to which adoption of these recommendations have impacted e-prescription medication safety. This project will be the first to combine and quantify e-prescription errors reported to two error reporting systems: 1) the Pharmacy and Provider prescribing Experience Reporting Portal (PEER) Portal; and 2) the Pharmacy Quality Commitment (PQC) system. From 2011 to date, collectively these systems have received approximately 40,000 reports of e-prescription problems nationally from chain and independent community pharmacists, which provides robust information from which to develop best practices for community pharmacists. These best practices can also be used to validate software design recommendations for e-prescribing systems.

This project is aligned with the Community Pharmacy Foundation Mission Statement because it will increase community pharmacists' awareness of the common problems associated with the use of e-prescribing and will support delivery of quality care. Additionally, it will be used to inform the Office of the National Coordinator (ONC) Health Information Technology Safety Center of common e-prescribing problems and potential solutions.

## II. Capacity, Readiness and Operations

The University of Cincinnati (UC) James L. Winkle College of Pharmacy, University of Arizona College of pharmacy, the National Alliance of State Pharmacy Associations (NASPA), and the Alliance for Patient Medication Safety (APMS) will partner to: develop; implement; interpret; and disseminate project results.

The primary investigator for this project is Dr. Ana Hincapie. Dr. Hincapie is responsible for leading all aspects of this project including design, execution, and dissemination. **Ana L. Hincapie PhD,** is an Assistant professor at the University Of Cincinnati College Of Pharmacy. She received her MS, and PhD in Pharmaceutical Economics, Policy and Outcomes from the University of Arizona. Her research occurs at the intersection of care quality and safety, the use of health information

technologies (HIT) and the evaluation on how HIT can help pharmacists provide better care. Dr. Hincapie has experience utilizing the mixed methods techniques that are required for the completion of this project. A large portion of her training, research, and professional experience relates to medication safety and quality improvement in community pharmacy. Specific research projects which have helped her develop the needed expertise for this project include: conducting a state level evaluation of clinician's use of and perceptions of how a health information exchange impacted quality and safety of care; using epidemiological methods to identify adverse drug events associated with the use of bisphosphonates; and evaluating medication errors associated with the use of e-prescribing systems in community pharmacies. Dr. Hincapie has managed extramural funding in the past, designing, implementing, evaluating and disseminating past studies; demonstrating her capacity of carrying out these roles for this project.

**University of Arizona**

**Terri Warholak, PhD,** Associate Professor at the University of Arizona, serves as an investigator within the Center for Health Outcomes and PharmacoEconomic Research. She received her BS, MS, and PhD from Purdue University. From 1990 to 1997, Dr. Warholak served as a Commissioned Officer in the United States Public Health Service where her clinical pharmacy experience included inpatient, ambulatory care and community practice and included 5 years in the Indian Health Service and an assignment at the Food and Drug Administration (FDA). She has over 15 years of experience participating in and leading studies that assess medication error reduction, HIT, and quality improvement. She served as Lead Researcher on the AHRQ funded project entitled "Maximizing the Effectiveness of e-Prescribing between Physicians and Community Pharmacies." Dr. Warholak is involved in e-prescribing and HIT projects on the state and national levels including the Arizona Medicaid Transformation Grant: Health Information Exchange and Health Record (HIeHR) Project and the EAzRx E-Prescribing Initiative for Arizona Health-e Connection. She serves as a consultant for the Food and Drug Administration Drug Safety and Risk Management (DSaRM) Advisory Committee and is a member of the United States Pharmacopeia (USP) Convention, Healthcare Quality Expert Committee.

**National Alliance of State Pharmacy Associations (NASPA)**

**Rebecca P. Snead, R.Ph** is the Executive Vice President and CEO of NASPA. Prior to assuming this position she was the Executive Director of the Virginia Pharmacists Association for over a decade. She is also the Secretary/Treasurer for the Alliance for Patient Medication Safety Pharmacy (APMS), a non-profit supporting entity to NASPA. NASPA, founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

**Alliance for Patient Medication Safety (APMS)**

**Tara Modisett** is the Executive Director of APMS and is responsible for developing, implementing and managing the APMS Patient Safety Organization (PSO). The APMS PSO has been listed by the Agency of Healthcare Research and Quality (AHRQ) since 2008. Modisett serves as NASPA's representative to the National Coordinating Council for Medication Error and Reporting and Prevention (NCC MERP) and on the Medication Safe Use Workgroup of the Pharmacy Quality Alliance (PQA). Ms. Modisett graduated from University of Richmond.

## III. Goals

The specific aims of this study are to:

1. Examine the frequency, type, and contributing factors of e-prescribing quality related problems reported to the Pharmacy Quality Commitment (PQC) System and the Pharmacy and Provider prescribing Experience Reporting Portal (PEER) Portal between 2011 and 2015;
2. Determine the potential impact of Surescripts e-prescribing "ideal prescription" guidelines adoption in preventing e-prescribing quality problems and errors;
3. Develop an error-prone medications list for electronic prescribing to warn pharmacists and prescribers about which medications are most-likely to necessitate a pharmacist intervention; and
4. Re-design re-open the Pharmacy and Provider prescribing Experience Reporting Portal (PEER) Portal.

## IV. Methods

**Aim 1: Examine the frequency, type, and contributing factors of electronic prescribing quality related problems reported to the Pharmacy Quality Commitment (PQC) System and the Pharmacy and Provider prescribing Experience Reporting Portal (PEER) Portal between 2011 and 2015.**

**Study design:** We will conduct a cross-sectional evaluation of all electronic (e-prescribing) incidents reported to two voluntary error-reporting systems: 1) PQC System; and 2) the PEER Portal.
The PQC System is owned and maintained by the Alliance for Patient Medication Safety (APMS). PQC enables pharmacist to document medication incidents (i.e., near misses, unsafe conditions, and errors that reached the patient) on a web-based report form. The report form collects information regarding the step of the medication use process where the incident was identified and corrected, the incident type, if e-prescribing was involved, and whether or not it reached the patient. In addition to collecting data, PQC generates dashboards that allow pharmacists to develop a plan for quality improvement. Incident reporting through PQC is voluntary but can only be used if a pharmacy level subscription is purchased. Currently, this data set contains over 40,000 quality related reports involving e-prescriptions. Although, e-prescribing is defined as the secure transmission and reception of prescribing information electronically, we will also include scripts sent electronically but received as a fax to understand the impact of faxes on the introduction of errors.

In order to expand the ability to report e-prescribing incidents without the need to subscribe to PQC, APMS developed a free web-based reporting form for e-prescribing incidents: The PEER Portal.[8] The PEER portal collected reports between 2009 and 2014.

**Data Collection:** We will extract all e-prescribing incidents reported to PQC and PEER Portal between January 2011 and January 2015.The following fields will be extracted from the PQC and PEER Portal data set: 1) date incident was reported; 2) type of prescription (new vs. refill); 3) where the incident was discovered (e.g., pharmacist final check, partner check, patient discovery, counseling, entry, filling, or delivered to patient); 4) incident type (i.e., incorrect drug, strength, directions, quantity, patient); 5) incident severity (i.e., levels range from 1-6 where 1 indicates that the event reached patient but caused no harm and 6 indicates patient death) and; 7) drugs involved (i.e., medication prescribed, medication dispensed, medication strength). Additionally, descriptive incident report data (i.e., open-ended data) will be extracted to further understand reasons for e-prescribing incidents.

**Data analysis:** Descriptive statistics will be calculated for all the variables of interest. Each incident will be classified as a near miss (i.e., incident did not reach the patient) or an error (i.e., event reached the patient). A multivariate logistic regression model be used to examine factors associated with the likelihood of errors and near misses (i.e., the dependent variable will be coded as either error or near miss). Comments about the incidents received in the open fields of each database will be examined and thematically coded by two using the Odukoya et.al[5] analytical framework for classifying incidents contributing factors.[10] A stepwise approach will be used to conduct the qualitative analysis. First, all incidents that reached patients with severity categories of 4, 5, 6, and 7 will be analyzed (approximately 150 incidents), then a random sample with replacement of 1% of all other severity level incidents will be analyzed (approximately 400 incidents). If saturation is not achieved, a subsequent random sample will be drawn and analyzed until saturation is achieved.

**Outcomes:** Outcomes will include the identification of the: number and types of error and near miss reports; factors associated with the likelihood of errors and near misses; and classification of contributing factors.

**Aim 2: Determine the potential impact of Surescripts e-prescribing "ideal prescription" guidelines adoption in preventing e-prescribing quality problems and errors.**

**Rationale:** E-prescribing standards and recommendations concerning how promote the ideal e-prescription orders have been created for vendors. The purpose of this aim is to: estimate the potential impact of adopting the "ideal e-prescribing order"[11] recommendations on e-prescribing incidents; and create recommendations for community pharmacists based on the "ideal order set."

**Study design:** A stratified random sample with replacement of 1% e-prescribing incidents (approximately 400 incidents) from data extracted for Aim 1 will be obtained.[9] The strata will include errors and near misses.

**Data Analysis**: The sample of incidents will be categorized as preventable or not preventable if the e-prescription had been compliant with the elements associated of the "ideal e-prescribing order" shown in Table 1. Two independent investigators will assess preventability and Kappa statistics will be calculated to determine interrater agreement.[12] Then reviewers will come to consensus when classification discrepancies are identified. Further qualitative analyses, as described in Aim 1, will be conducted on incidents classified as non-preventable by using the open text data from the incident report. Thematic coding will be used to elucidate reasons the prescription incident could not be prevented by adoption of an ideal order standard.

**Sample size**: Assuming a conservative agreement of 30% between the two reviewers with a 20% relative error a minimum sample size of 278 incidents would be need to achieve valid interrater reliability results. A 1% sample of incidents will exceed the minimum sample size required.[13]

**Outcomes:** Outcomes will include: proportion of e-prescriptions that would be considered preventable if compliant with the elements of the "ideal e-prescribing order;" and reasons why incidents designated as not preventable could not be prevented by adoption of the ideal order standard.

**Table 1. Surescript's recommendations for elements of an "ideal e-prescribing order"**

| Element | Description |
|---|---|
| Drug Description | Elimination of "free-text" data<br>Standardized Drug Descriptions |
| Drug Identifiers | Accurate National Drug Code (NDC) and RxNorm drug identifiers<br>Consistent sending of RxNorm Clinical drug component RXCUI |
| Patient Directions (Sig) | Complete and unambiguous patient directions<br>Implementation of Structured & Codified Sig format |
| Quantity/Quantity Qualifiers | Valid and appropriate prescription quantities<br>Metric and non-generic quantity qualifiers only |
| Days Supply | Accurate days supply information that is not conflicting with other prescription data elements |
| Coordination of Benefits | Accurate Patient Benefit information from the Health Care Eligibility Benefit Inquiry and Response<br>Inclusion of Pharmacy Benefits Manager (PBM) Unique identifier (ID) |
| Prescriber & Pharmacy Directories | Accurate and up-to-date prescriber and pharmacy information in the Surescripts directory |
| Duplicate Content/Message IDs | No duplicate e-prescription content or message IDs |
| Prescription (Rx) Change/Rx Cancel | Network-wide implementation of Rx Change and Cancel Rx messages |
| Notes to Pharmacist | Codified data text strings<br>Free text restricted to pharmacist information only |
| Electronic Prescription of Controlled Substance (EPCS) | Full Implementation and Deployment of EPCS functionality |

**Aim 3: Develop an error-prone medications list for e-prescribing to warn pharmacists and prescribers about which medications are most-likely to necessitate a pharmacist intervention.**

**Rationale:** Look-alike/Sound-alike (LASA)[14] medications may facilitate e-prescribing incidents. While a LASA list was created for hand-written prescriptions, none exists specifically for the e-prescribing process. Additionally, unconventional pharmaceutical preparations (e.g., otic and ophthalmic suspensions, inhalers, some salts) may be particularly prone to errors. The purpose of this aim is to compare e-prescribing incidents reported to the PQC and PEER databases with the Institute for Safe Medication Practices (ISMP) LASA list to identify additional e-prescribing medication pairs that should be included. This aim seeks to identify the most common incident prone medications based volume and severity of e-prescription incident reports.

**Study Design:** The incidents database created for Aim 1 will be used to identify the medication pairs most prone to LASA incidents during the e-prescribing process.

**Data Analysis**: Incidents categorized as incorrect medication, incorrect dose or unit, and incorrect route will be evaluated**.** Medications identified as being prone to LASA e-prescribing errors will be compared with the ISMP LASA drug list.

**Outcomes:** Outcomes will include: identifying and recommending additional medication pairs that should be included on the ISMP LASA list; and informing prescribers and pharmacists about medication pairs that should be included on the ISMP LASA list.

**Aim 4: Re-design re-open the Pharmacy and Provider prescribing Experience Reporting Portal (PEER) Portal.**

**Rationale:** Voluntary incident reporting systems play an essential role in efforts to detect quality and safety related events. The PEER Portal was designed with support from the Community Pharmacy Foundation to generate a place where pharmacist and prescribers could anonymously report safety events associated with e-prescribing. PEER portal data support system improvements as feedback on reporting is disseminated through NASPA and APMS. As e-prescribing software, standards, policies and procedures evolve, it is essential to modify the PEER portal to facilitate reporting by community pharmacists. The purpose of this aim is to re-open the reporting portal to capture safety event data while, at the same time, streamlining the reporting process.

**Study Design:** During the data management and data analyses of Aims 1 to 3, investigators will take notes to identify areas of the PEER reporting system that generated ambiguities in incident classification, as well as data fields that were never or rarely used. Based on the notes, one investigator will create a list of suggested changes to the data fields of the PEER Portal. The list will evaluated independently by two other members of the team. After consensus is reached on proposed changes, the new reporting system will be tested on 10–20 open ended comments drawn randomly from the sample created for Aim 1.Two investigators independently will read the open text report and will test the revised version of the PEER portal.

**Data Analysis:** Pairwise agreement on the PEER portal structured data fields by the two investigators will be estimated. For the incident type and incident severity categories, inter-rater reliability will be determined calculating Kappa statistics. For contributing factors, where a given incent may have multiple contributing factors, pairwise agreement for the two investigators will be defined as the number of agreed category assignments to an incident divided by the number of assignments of either investigator (agreement/agreement + disagreement).[15]

**Outcomes:** Outcomes will include: 1) a revised and re-opened PEER reporting system; and 2) a compiled list of best practice recommendations for community pharmacists and prescribers that integrates the work of Odukoya et al[5], Warholak et al[6], Hincapie et al[16], and Rupp et al[17] with results generated from Aim 1 to Aim 3.

## V. Dissemination Plan

In addition to submission of a project report to the Foundation, we will disseminate the results with numerous pharmacy and healthcare stakeholders including the Institute of Medicine, Office of the National Coordinator, Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs, Electronic Health Records incentive programs, and patient safety organizations. The report will be distributed to all state pharmacy associations in collaboration with NASPA. A proposal for podium presentation will be submitted to the American Pharmacists Association (APhA). The Power Point slides will be also distributed to all state pharmacy associations as well as made available on the APMS and NASPA websites. Distribution of the final report and slides deck will also occur through social media outlets. The renovated PEER portal will be re-launched by APMS and NASPA.

## IV. Timeline

| Task | Month | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| **Aim 1** | | | | | | | | |
| Institutional Review Board (IRB) approval | **x** | | | | | | | |
| Data acquisition | | **x** | | | | | | |
| Data Management | | **x** | **x** | | | | | |
| Quantitative data analysis Aim 1 | | | | **x** | | | | |
| Qualitative data analysis Aim 1 | | | | **x** | **x** | | | |
| **Aim 2** | | | | | | | | |
| Quantitative data analysis Aim2 | | | **x** | | | | | |
| Qualitative data analysis Aim 2 | | | | **x** | **x** | | | |
| **Submit Midterm Report** | | | | **x** | | | | |
| **Aim 3** | | | | | | | | |
| Qualitative data analysis Aim 3 | | | | | | **x** | | |
| **Aim 4** | | | | | | | | |
| Re-design PEER Portal | | | | | | | **x** | **x** |
| Final report reparation | | | **x** | **x** | **x** | **x** | **x** | **x** |
| **Submit final report** | | | | | | | | **x** |

## V. Budget

| Category | Effort | Cost | Total |
|---|---|---|---|
| **University of Cincinnati** | | | |
| Hincapie Salary/Benefits | 10% *8 Months | **$13,600** | **$ 19,654** |
| Student Salary/Benefits | 50% *8 Months | **$6,054** | |
| **APMS/NASPA** | | | |
| Modisett Salary /Benefits | 2% *8 Months | **$2,800** | **$ 2,800** |
| **University of Arizona** | | | |
| Warholak Salary/Benefits | 7% *8 Months | **$7,775** | **$7,775** |
| **Total Budget Requested** | | | **$ 30,229** |

Additional funds from Dr. Hincapie's research start –up funds:

- Travel Funds $1,500
- Data Acquisition and IT support $10,000 *(Data Acquisition and IT support will be Provided by APMS)*

University of Cincinnati

-**Dr. Hincapie** will serve as principal investigator (PI). The PI will coordinate and supervise the research as described in the proposal and the student researcher. She will assure: timely and thorough analysis and interpretation of data; integration and synthesis of study findings; and preparation of interim and final reports. Dr. Hincapie will actively seek to disseminate the study findings at scientific meetings and will prepare scientific manuscripts for peer-reviewed journals.

-**TBD undergraduate research assistant**: The student researcher will assist Dr. Hincapie in data cleaning and will be responsible for maintaining the data files to be utilized in the project (i.e., merging files to create datasets (with the help of Dr. Hincapie), and creating and documenting new variables). The student will also assist in analyzing data as well as in preparing reports, abstracts and manuscripts.

University of Arizona

-The University of Cincinnati will contract with **Terri Warholak, PhD** at the University of Arizona. Dr. Warholak will provide consultation on the design of the study and will assist Dr. Hincapie in the qualitative analysis of the project. She has worked and published in this area extensively will be a critical contributor to this research.

**APMS -NASPA**

-The University of Cincinnati will contract with APMS and NASPA. APMS will provide the data from PQC System and PEER Portal, as well as it will provide IT support. **Tara Modisett** will provide administrative support to the project. **Rebecca P. Snead, RPh** will assist in the dissemination of the study results through NASPA members and provide executive consultation.

**Payment Schedule**

| | | |
|---|---|---|
| Project Initiation: | 50% | ($15,114.50) |
| Receipt of Final Midterm Report (month 4): | 35% | ($10,580.15) |
| Receipt of Final Report (month 8): | 15% | ($ 4,534.35) |

**CPF DOCUMENTATION ITEMS**

| Item | Response |
|---|---|
| IRB Required | Yes. It will go under review through the University of Cincinnati, Human Research Protection Program and will most likely be deemed "exempt." |
| Sustainability | This project will be sustainable in the future because the reporting portal will remain available on the APMS website. APMS will monitor and reports future events to the community through various channels including NASPA. |
| Transferability | This project is transferable because results and recommendation from this study can be incorporated by community pharmacists. |
| Future implications | Future research and pharmacy/pharmacist opportunities will be created by increasing awareness of e-prescribing related incidents. It will inform stakeholders on the potential impact of standardized order sets on medication safety. |

**BUSINESS PLAN**

| AIMS | KEY ACTION STEPS | DATA SOURCE | OUTCOME & EVALUATION | PERSON RESPONSIBLE | COMMENTS/ NOTES |
|---|---|---|---|---|---|
| **AIM 1.** Examine the frequency, type, and contributing factors of electronic prescribing quality related problems reported to the Pharmacy Quality Commitment (PQC) System and the Pharmacy and Provider prescribing Experience Reporting Portal (PEER) Portal | **A1a** Prepare and Submit IRB for approval | None needed | Sign data use agreement<br><br>IRB Approved | Drs. Hincapie | To expedite the process, IRB submission will occur at the same time as grant submission |
| | **A1b** Obtain data PQC and PEER data | PQC and PEER portal data | Creation of analytic data file with combined data | Dr. Hincapie | |
| | **A1c** Complete quantitative analysis | Analytic data file created in A1b | Identification of number and types of error and near miss reports<br>Identification of factors associated with the likelihood of errors and near misses | Drs. Hincapie and Warholak | |
| | **A1d** Complete qualitative analysis | Comments about the incidents received in the open fields in the data file in A1b | Classification of contributing factors | Drs. Hincapie and Warholak | |
| **AIM 2.** Determine the potential impact of Surescripts e-prescribing "ideal prescription" guidelines adoption in preventing e-prescribing quality problems and errors | **A2a** Sampling analytic data file | Analytic data file created in A1b | | Dr. Hincapie | |
| | **A2b** Independent classification of incidents | Analytic data file created in A1b | Proportion of preventable e-prescribing if adoption of 'ideal order set' | Drs. Hincapie and Warholak | |
| | **A2c** Consensus agreement and analysis of incidents considered not preventable by "ideal order set" adoption | Analytic data file created in A1b | Identification of reasons why incidents designated as not preventable could not be prevented by adoption of the ideal order standard | Drs. Hincapie and Warholak | |
| **AIM 3.** Develop an error-prone medications list for e-prescribing to warn pharmacists and prescribers about which medications are most-likely to necessitate a pharmacist intervention | **A3a** Comparison of the with the ISMP LASA drug list with Medications identified as being prone to LASA e-prescribing errors | Analytic data file created in A1b | Identification of additional medication pairs that should be included on the ISMP LASA list | Dr. Hincapie | |

| | | | | | |
|---|---|---|---|---|---|
| | **A3b** Creation of a distributable list of medication pairs that should be included to the ISMP LASA list | List of LASA medications omitted created in A3a | Informing prescribers and pharmacists about medication pairs that should be included to the ISMP LASA list | Dr. Hincapie | |
| **AIM 4**. Re-design re-open the Pharmacy and Provider prescribing Experience Reporting Portal (PEER) Portal. | **A4a** Creation of a list of suggested changes to the data fields of the PEER Portal | Comments from investigator notes from Aims 1 to 3, that identified areas of the PEER reporting system that generated ambiguities in incident classification, as well as data fields that were never or rarely used | A preliminary list of suggested changes to the data fields of the PEER Portal | Dr. Hincapie and Ms. Snead | |
| | **A4b** The list will evaluated independently by two other members of the team and consensus reached | Comments from investigator notes from Aims 1 to 3, that identified areas of the PEER reporting system that generated ambiguities in incident classification, as well as data fields that were never or rarely used | A final list of suggested changes to the data fields of the PEER Portal<br><br>Make changes suggested | Drs. Hincapie and Warholak and Ms. Snead | |
| | **A4c** Test the new reporting system and make necessary edits | Analytic data file created in A1b | APMS postal ready for re-opening | Dr. Hincapie and Ms. Snead | |
| | **A4d** Advertise the opening of the portal | None needed | Portal re-opened on APMS | Dr. Hincapie and Ms. Snead | |

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RE: "Comprehensive Analysis of Electronic Prescribing Quality Related Incidents"

July 10, 2015

Dear Ms. Jones:

As Executive Vice-President & CEO of the National Alliance for State Pharmacy Associations (NASPA), I am pleased to submit a letter of support for the "Comprehensive Analysis of Electronic Prescribing Quality Related Incidents" project.

NASPA looks forward to collaborating with you on this important research to improve patient safety.

Rebecca P. Snead

Executive Vice President & CEO
National Alliance of State Pharmacy Associations