

## PUBLIC HEALTH

# An Assessment of State Board of Pharmacy Legal Documents for Public Health Emergency Preparedness

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**Objective.** To estimate pharmaceutical emergency preparedness of US states and commonwealth territories.

**Methods.** A quantitative content analysis was performed to evaluate board of pharmacy legal documents (ie, statutes, rules, and regulations) for the presence of the 2006 Rules for Public Health Emergencies (RPHE) from the National Association of Boards of Pharmacy's (NABP) Model Pharmacy Practice Act.

**Results.** The median number of state-adopted RPHE was one, which was significantly less than the hypothesized value of four. Rule Two, which recommended policies and procedures for reporting disasters, was adopted significantly more than other RPHE. Ten states incorporated language specific to public health emergency refill dispensing, and among these, only six allowed 30-day refill quantities.

**Conclusion.** Based on the 2006 NABP model rules, it does not appear that states are prepared to expedite an effective pharmaceutical response during a public health emergency. Boards of pharmacy should consider adding the eight RPHE to their state pharmacy practice acts.

**Keywords:** pharmacy, disaster, public health, emergency

## INTRODUCTION

The 2005 hurricane season revealed major challenges for medical and public health disaster response systems. In steady succession, Hurricanes Dennis (July), Katrina (August), Rita (September), and Wilma (October) caused significant disruption to the Gulf Coast region, displacing more than one million people<sup>1</sup> and resulting in more than 2100 deaths and \$USD 112 billion in damage.<sup>2</sup> The cumulative effect of these natural phenomena severely strained existing medical and public health infrastructure, where patient access to chronic care services (including medications)<sup>3</sup> became a principal concern.<sup>1</sup>

In response to the vulnerabilities revealed by the Gulf Coast storms of 2005, the National Association of Boards of Pharmacy (NABP) convened a task force to address the pharmacy-related aspects of the response.<sup>4</sup> The task force observed that, though state boards of pharmacy routinely facilitated access to substantial amounts of web-based resources such as license verification and renewal, pharmacy laws, and continuing education requirements, little information was readily available

regarding statutory or regulatory requirements governing pharmacy services in times of disaster.<sup>4</sup> As a result, the task force drafted the "Emergency and Disaster Preparedness and Response Planning Guide for Boards of Pharmacy."<sup>5</sup> By offering draft language suitable for incorporation into state pharmacy practice acts, the guide provided a statutory and regulatory framework for states to use to proactively prepare for future disasters.

It is not uncommon for executive authorities (ie, state boards of pharmacy or state governors) to issue emergency declarations suspending, adopting, or invoking specific rules in times of disaster.<sup>6-9</sup> In lieu of instituting emergency measures post hoc, such authorities recommend that states establish legal measures a priori,<sup>10</sup> allowing the pharmacy and health care communities the benefit of proactively anticipating the regulatory environment when emergency rules are invoked. Since 2006, state boards of pharmacy have had access to guide recommendations, including the eight Rules for Public Health Emergencies (RPHE) in the Model Pharmacy Practice Act.<sup>5</sup> At this point, however, the extent to which the RPHE have been incorporated into state pharmacy legal documents is unknown. As in the aftermath of the 2005 hurricane disasters, the actuating question for state boards of pharmacy remained in 2015: is adequate pharmacy-specific legal documentation currently instituted to

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facilitate the provision of pharmacy services during a disaster?

The purpose of this research, therefore, was to assess the pharmaceutical preparedness of US states and commonwealth territories by evaluating pharmacy regulatory documents for the presence of the eight recommended RPHE.

## METHODS

A quantitative content analysis of board of pharmacy legal documents (ie, statutes, rules, and regulations available through board websites) was performed to assess the level of pharmaceutical preparedness of each US state and commonwealth territory. For this analysis, pharmaceutical preparedness was defined as the presence of the eight recommended RPHE (Table 1) in pharmacy-related statutes or board rules and regulations. Each board of pharmacy website was identified and accessed through the NABP website, which maintains active web links to all member boards. (In an effort to focus on preparedness in the United States, member boards from Australia, Canada, and New Zealand were not included in the analysis.)

Data were collected and evaluated during the months of December 2014 and January 2015. To reduce the risk of overlooking information, board of pharmacy documents were reviewed on three separate occasions for the presence of study variables. Because this analysis did not involve human subject experimentation, institutional review

board approval was considered unnecessary and was neither sought nor obtained.

In addition to the eight RPHE, other variables were identified and included in the analysis. The number of states with (and types of) emergency refill limits (ie, 30-day, 15-day, 10-day, 7-day, and 72-hour) were extracted from board of pharmacy legal documents, and information regarding the number of state disaster declarations since 1953—the earliest date of record—was accessed through the Federal Emergency Management Agency (FEMA) website.<sup>11</sup> These variables were analyzed by NABP district<sup>12</sup> (Table 2) to provide a more comprehensive perspective of state pharmaceutical preparedness.

Because count data can often follow a nonGaussian distribution,<sup>13</sup> data were tested for normality and, where warranted, analyzed using nonparametric statistical tests. Descriptive and inferential analyses, including sign, chi-square, and Spearman correlation tests were conducted using SAS, v9.4 (SAS Institute Inc., Cary, NC). Microsoft Excel was also used to examine variables in bar, pie, and line graphs. Significance was set at an alpha level of 0.05.

## RESULTS

Figure 1 shows the total number of RPHE adopted by state boards of pharmacy. The mean, standard deviation, median, and mode values reflecting the number and percentage of RPHE adopted by state boards were 1.4 (17.8%), 1.6 (20.1%), 1 (12.5%), and 0, respectively. Results of

Table 1. The Eight Rules for Public Health Emergencies (RPHE) from the National Association of Boards of Pharmacy<sup>5</sup>

1. Pharmacies should establish procedures for storing and dispensing drugs in disaster scenarios.<sup>a</sup>
2. Pharmacies should establish policies and procedures for reporting disasters to the state board within 10 days of occurrence.<sup>a</sup>
3. Pharmacists may dispense emergency drugs pursuant to an emergency drug order as long as a prospective drug regimen review can be conducted and a record of the prescription maintained.
4. I. Pharmacists may dispense a 30-day refill supply (during the length of time a disaster is declared) without practitioner authorization if the pharmacist (a) considers it an essential medication for the patient, (b) maintains a record of the refill, and (c) informs the patient or recipient that practitioner authorization is required for future refills.  
II. Pharmacists may also modify therapy or dispense a refill amount that best addresses the needs of the patient during the length of time a disaster is declared. The same conditions (ie, sections (a) through (c) above) also apply.
5. Pharmacists, pharmacy technicians, and wholesalers not licensed in the state in which the disaster occurs may dispense drugs in disaster areas as long as (a) the licenses can be verified and found to be in good standing and (b) the professionals are engaged in disaster relief efforts.
6. Pharmacies not licensed in the state in which the disaster occurs and pharmacies licensed within the state but affected by the disaster may temporarily relocate or operate as mobile pharmacies during the length of time a disaster is declared.
7. Pharmacists should keep a record of drugs considered unfit for use as a result of disaster and dispose of them through an appropriate vendor.<sup>b</sup>
8. Pharmacies should notify the Drug Enforcement Agency (DEA) of drug theft and submit appropriate DEA forms to document theft of controlled substances.<sup>b</sup>

<sup>a</sup>These rules are included in the Emergency and Disaster Preparedness and Response Planning Guide as “Model Rules for the Practice of Pharmacy” instead of RPHE.<sup>5</sup> Due to the disaster-oriented nature of the rules and for simplicity, these rules are included as RPHE

<sup>b</sup>Numbers 7 and 8 of the recommended RPHE are listed as comments in the Emergency and Disaster Preparedness and Response Planning Guide but are included in this analysis as separate rules<sup>5</sup>

Table 2. United States National Association of Boards of Pharmacy (NABP) District Composition<sup>12</sup>

District 1	Connecticut, Maine, Massachusetts, New Brunswick, New Hampshire, Rhode Island, Vermont
District 2	Delaware, District of Columbia, Maryland, New Jersey, New York, Pennsylvania, Virginia, West Virginia
District 3	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virgin Islands
District 4	Illinois, Indiana, Michigan, Ohio, Wisconsin
District 5	Iowa, Minnesota, Nebraska, North Dakota, South Dakota
District 6	Arkansas, Kansas, Louisiana, Missouri, Oklahoma, Texas
District 7	Alaska, Idaho, Montana, Oregon, Washington, Wyoming
District 8	Arizona, California, Colorado, Guam, Hawaii, Nevada, New Mexico, Utah

the sign test indicated that the median proportion of RPHE adopted by the state boards of pharmacy (12.5 %) is significantly less than 50% ( $M=-23.5, p<0.001$ ).

Figure 2 trends the number of RPHE adopted by NABP district ( $X^2=23.7, p=0.001$ ) with the number of disasters that have occurred in each district since 1953 ( $X^2=612, p<0.0001$ ). There was a close trend between disasters and RPHE adopted by NABP district (Figure 2) and a significant positive association overall between the number of disasters and RPHE adopted (Spearman  $r=0.32, p=0.02$ ). Figure 3 also shows the number of state boards of pharmacy that adopted each RPHE ( $X^2=15.8, p=0.03$ ).

Data also show that emergency refill quantities were not uniform across state boards of pharmacy (Figure 4). Although significantly fewer states (10) incorporated language specific to public health emergency refill dispensing ( $X^2=20.2, p<0.0001$ ), data nonetheless indicate that, among all states issuing emergency refills (regardless of the presence of public health emergencies), certain refill quantities were adopted proportionately more by state boards of pharmacy ( $X^2=44.8, p<0.0001$ ).

## DISCUSSION

Prior to this research, the extent to which RPHE were incorporated into state pharmacy legal documents was largely unknown. Our study suggests that most states are without adequate legal documentation to facilitate the provision of pharmacy services in disaster. Data show that 49 of 54 US states and territories adopted less than half the recommended RPHE, and of these, 20 adopted none of the RPHE. Other research suggests similar results.<sup>14,15</sup> In a cross-sectional study of state board of pharmacy representatives, Lowe analyzed information regarding the presence of disaster-specific regulations in state pharmacy practice acts.<sup>15</sup> While only 18 states reported useful information, data indicated that disaster-specific legal measures were inconsistently adopted among boards of pharmacy and would likely remain unchanged in the foreseeable future.<sup>15</sup>

To illustrate the real and practical difficulties that can manifest as a result of inadequate legal support, a report by the Centers for Disease Control and Prevention (CDC) suggests that while public health preparedness has improved since 2001, state governments continue to face operational challenges with expediting

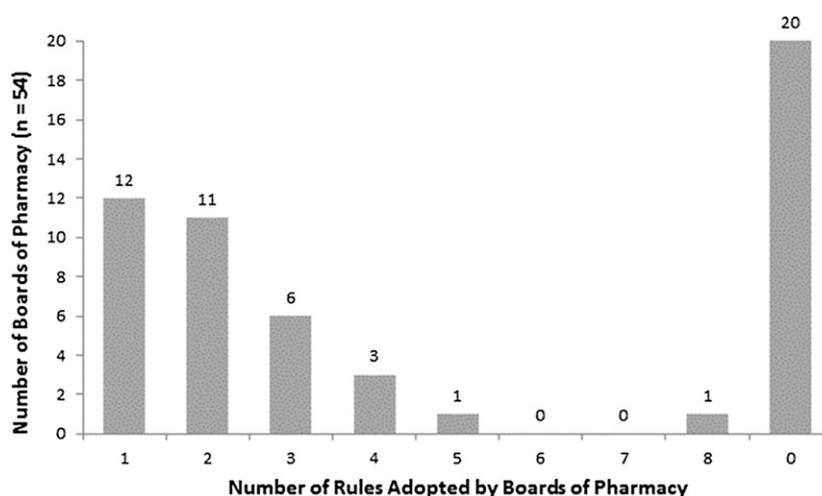
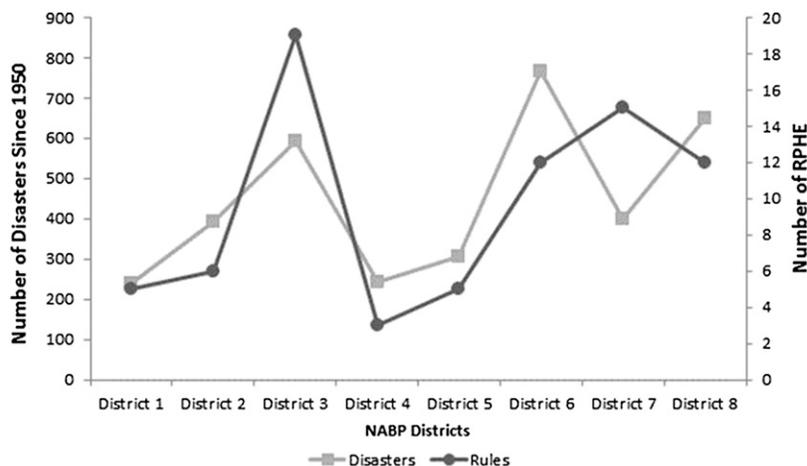


Figure 1. Total Number of RPHE Adopted by State Boards of Pharmacy (n=54).



Note that the total number of RPHE adopted by boards of pharmacy within each NABP district represents the sum of all RPHE across constituent boards. Thus, while there are only eight RPHE, the total number of RPHE adopted by all boards within a district may sum to be greater than eight.

Figure 2. Trends in Disasters and Rule Adoption among National Association of Boards of Pharmacy (NABP) Districts.

the deployment of assets from local, state, and federal medication caches.<sup>14,16</sup> The lack of adequacy and consistency in disaster-specific regulations may increase confusion among licensed pharmacists and inherently discourage volunteer participation in disaster-related activities.<sup>15</sup> For these reasons (and considering that pharmacists must prepare for and pass jurisprudence examinations in each state for licensure), we strongly encourage states without disaster-specific pharmacy statutes to incorporate appropriate legal language into their pharmacy practice acts.<sup>17</sup> Minimally, states should have adequate regulatory language promulgated by boards of pharmacy (ie, NABP RPHE) that address policies and procedures governing pharmacy practice in disasters.<sup>17</sup> Until that point, inadequate state-level legal support for disaster-related responsibilities will continue to negatively impact patient safety.<sup>18,19</sup>

Although practical disaster-specific considerations (eg, record-keeping, medication disposal, refill dispensing,

and emergency prescription drug order processing) for pharmacist volunteers depend on legal mechanisms within each state,<sup>20</sup> federal-level measures can be used to protect volunteers from liability.<sup>20,21</sup> For example, the Public Readiness and Emergency Preparedness (PREP) Act can be invoked by the US Secretary of Health and Human Services to provide immunity from problems arising from the use of medical countermeasures dispensed by pharmacists (and other authorized personnel).<sup>20,21</sup> The PREP Act also provides a regulatory mechanism to conduct basic, clinical, and administrative research on medical countermeasures.<sup>21</sup> Emergency Use Authorizations (EUA) are granted by the Food and Drug Administration (FDA) commissioner and provide for the emergency use of unapproved medical products and approved medical products for unapproved indications.<sup>21</sup> Each EUA is associated with unique provisions governing its issuance and is effective until terminated by the FDA.<sup>21</sup> The Shelf Life Extension

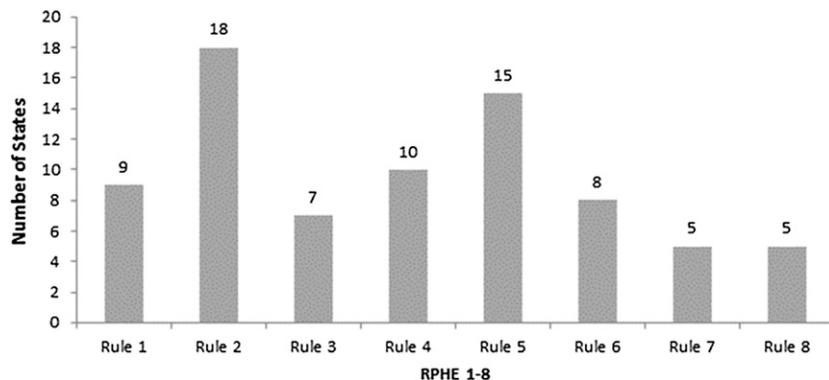


Figure 3. Number of Boards of Pharmacy that Adopted Specific Rules for Public Health Emergencies (RPHE) Rules.

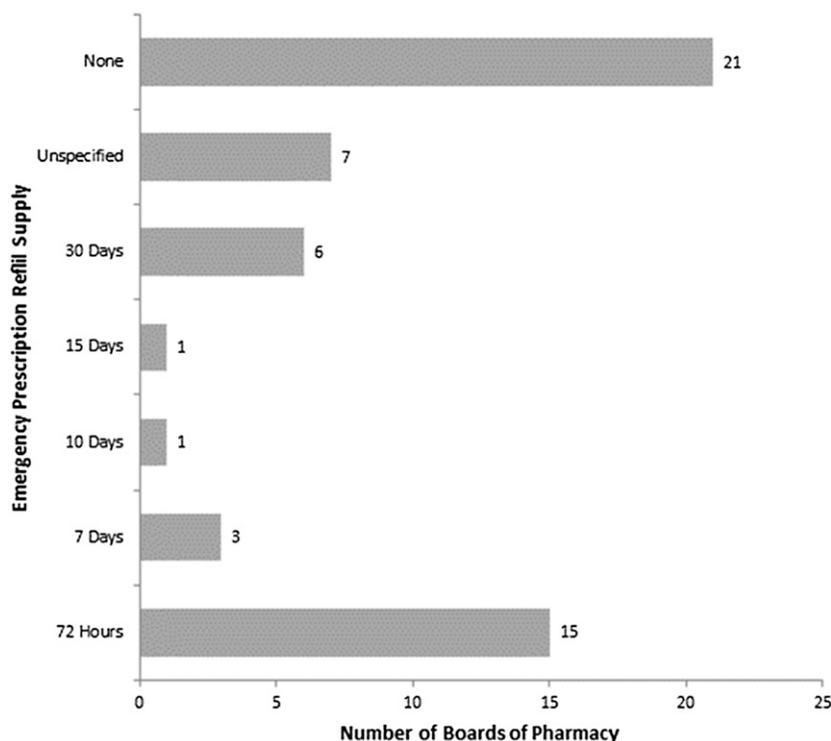


Figure 4. Emergency Refill Quantities Authorized by Boards of Pharmacy.

Program (SLEP) is a mechanism used in conjunction with an EUA to promote greater access to medical countermeasures during disasters. Once labels expire, medical countermeasures are tested for potency to determine their eligibility for extended shelf life.<sup>20</sup> Investigational New Drug and Investigational Device Exemption applications can be employed in disasters to facilitate use of unapproved medications or medication devices.<sup>21</sup> Like the SLEP, these applications are typically accompanied by the issuance of an EUA.<sup>21</sup> While these legal tools serve important functions for pharmacist volunteers, protective mechanisms are critical in federally-declared disasters. Their use for point-of-dispensing administrative concerns, which are governed by individual state jurisdictions, are of limited significance.

Interestingly, state disaster declarations and RPHE adoption trend closely when analyzed by NABP district (Figure 2), suggesting that rule adoption may be a function of geographic location and disaster occurrence (Spearman  $r=0.32$ ,  $p=0.02$ ). In terms of the number of RPHE adopted by boards of pharmacy, NABP District 3, which encompasses the southeastern states and Caribbean territories, is best prepared compared to other districts to expedite a pharmaceutical response to disaster ( $p=0.001$ ). This relatively heightened attentiveness to pharmaceutical preparedness may be a result of the potential for socio-medical sequelae associated with seasonal recurrence of

hurricanes and subsequent weather (including wind and tornado damage, hail showers, and flooding).

In the aftermath of Hurricane Katrina, for instance, several southern states including Alabama instituted legal measures to accommodate the prescription needs of a large influx of disaster refugees.<sup>6,9</sup> Some of these measures allowed pharmacists to issue 30-day refill quantities,<sup>6</sup> granted emergency temporary pharmacist licenses,<sup>9</sup> reactivated inactive pharmacist licenses,<sup>9</sup> and allowed remote pharmacies to provide services to the population,<sup>9</sup> among others. While District 3 adopted a significantly greater number of RPHE than other districts, District 6 was associated with the most state disaster declarations ( $p<0.0001$ , Figure 2), indicating that despite closely parallel trends between disasters and RPHE, districts that experienced the most disasters did not necessarily adopt the most RPHE.

Among the eight RPHE, Rule 2 (pharmacies should establish policies and procedures for reporting disasters to the state board within 10 days of occurrence<sup>5</sup>) has been adopted by the most state boards of pharmacy ( $p=0.03$ ), followed by Rule 5 (pharmacist, pharmacy technicians, and wholesalers not licensed in the state in which the disaster occurs may dispense drugs in disaster areas as long as (a) the licenses can be verified and found to be in good standing, and (b) the professionals are engaged in disaster relief efforts,<sup>5</sup> Figure 3). Considering the predominance

of online license verification tools available through board of pharmacy websites and the importance of disaster notification and license information for the various boards and their constituents, these findings may be indicative of the importance of communication and information sharing, especially during times of disaster.

Twenty-one states have no provision for public health emergency refill dispensing, and fifteen states limit refill quantities to a 72-hour emergency supply (Figure 4), a finding consistent with other research.<sup>17</sup> The importance of instituting legal language in support of 30-day refill quantities cannot be overstated, particularly as the primary health need of most disaster refugees is replacement prescription medications.<sup>22</sup> It is interesting that several states with statutory provisions for only 72-hour emergency (ie, nonpublic health emergency) refill quantities have in the past instituted temporary measures allowing 30-day refill quantities in response to public health crises.<sup>6,8,23</sup>

Pharmacy legal documents used in the analysis were available through board of pharmacy websites only. Although these sources are maintained by the boards, they may not be current or inclusive of all documents related to RPHE and pharmaceutical preparedness. Additionally, the likelihood that some material might have been overlooked in the data collection process cannot be entirely excluded, even as all board of pharmacy legal documents were reviewed multiple times to limit this possibility.

Additional variables should be identified and queried with existing data to establish a more comprehensive assessment of state pharmaceutical preparedness. For example, the existence of board policies and procedures regarding: (1) dispensing of drug samples and blood clotting agents; (2) drug distribution in emergencies; (3) waivers for controlled substance dispensing reporting; (4) closing of pharmacies without notifying boards of pharmacy, (5) public health powers of state governors; (5) tele-pharmacy subcontracting services in disasters; and (6) recruiting, training, and deploying in-state pharmacist volunteers should be considered.

In light of this study and the universal availability of the RPHE, each state board of pharmacy may want to review its disaster-specific regulatory provisions to determine if current pharmaceutical preparedness language is adequate to meet the exigencies of public health emergencies. For states that discover significant gaps in this element of their preparedness blueprint, interested parties and stakeholders may need to lobby their boards of pharmacy and legislatures for the inclusion of the RPHE in their pharmacy practice acts.

## CONCLUSION

Based on the 2006 RPHE, states do not seem prepared to expedite an effective pharmaceutical response during a public health emergency. During times of disaster, access to and use of state legal guidance documents for pharmaceutical response activities is vital for pharmacy personnel. Without legal guidance instituted in advance of disaster, the pharmaceutical response can be unintentionally mismanaged and result in undue harm to both patients and providers, with potential legal ramifications surfacing during the postresponse phases of the disaster. It is imperative, therefore, that state governments adopt predisaster guidance measures that can be quickly invoked to provide pharmacists and institutions appropriate legal protections to effectively respond to disasters.

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