National Evaluation of Prescriber Drug Dispensing

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Objective To describe the legal, professional, and consumer status of prescribers dispensing legend and over-the-counter drugs in the United States.

Methods Legal and academic databases were searched to identify those states that permit prescribers to dispense medications to patients and any limitations on such practice. In addition, prescribers and patients-consumers were surveyed to learn about the prevalence and perceptions of such practice. The use of drug samples was explicitly excluded from the study.

Main Results Surveys were obtained from 556 physicians, 64 NPs, and 999 patient-consumers of drugs dispensed by prescribers. Forty-four states authorize prescriber dispensing. Midlevel practitioners (i.e., NPs and physician assistants) are authorized to dispense in 43 states. Thirty-two states do not require dispensing prescribers to compete additional registration to dispense medications, and 30 states require some level of compliance with pharmacy practice requirements. Prescriber dispensing is common, independent of patient age or insurance coverage. Prescriber dispensing appears driven by physician and patient perceptions of convenience and cost reductions. Future dispensing is likely to increase due to consumers’ satisfaction with the practice. Consumer self-reported adverse drug reactions (ADRs) were equivalent between pharmacist- and physician-dispensed drugs, but urgent and emergency clinic ADR consultations were slightly lower with physician dispensing.

Conclusions Prescriber dispensing is firmly entrenched in the U.S. health care system, is likely to increase, does not appear to increase ADRs, and may reduce urgent care and emergency department visits. The reduction in urgent care and emergency department visits requires further study to confirm these preliminary findings.

Key Words legal, public health, prescriber dispensing.

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Dispensing of medicines has occurred throughout the centuries through a variety of channels. As commonly defined, dispensing means “to prepare and distribute medicines to those who are to use them” or to “to give out medicine and other necessities to the sick, and to fill a medical prescription.”1, 2 This practice has been a role of the medical and pharmacy professions since ancient times and has been under close scrutiny by health care and society throughout the centuries.1 Historically, prescriber dispensing rates dropped from 39% of prescribers in 1923 to only 1% in 1986 because the practice was not seen in a favorable light due to ethics, conflict of interest, patient welfare, and economics.3, 4 However, in the last 3 decades, there appears to have been a resurgence in prescriber dispensing rates, although not without controversy.4
The controversy of prescriber dispensing rose to prominence in the 1980s. Many publications focused on physician professional autonomy, conflict of interest, patient acceptance, potential for harm, and economic competition between the medical and pharmacy professions.\textsuperscript{5–8} Federal and state legislative initiatives were introduced for and against nonpharmacist dispensing.\textsuperscript{9} Additional publications described the professional role separation, practice privileges, and the regulatory basis for prescriber dispensing.\textsuperscript{4, 10–12} However, these publications did not offer specific citations to statutory or regulatory authorization for prescriber dispensing. They also did not systematically address health care providers’ beliefs and behaviors around the practice or consumer perceptions of and reactions to this drug-dispensing practice.

In 2012, the Utah legislature in association with the Division of Occupational and Professional Licensing initiated an inquiry into the statutory basis and scope of legally authorized prescriber dispensing in the United States. To this end, the three studies reported here were conducted to provide a comprehensive overview of the practice. The objective of the first study was to provide a point-in-time description of state statutes and regulations that do or do not allow prescribers to dispense medications to their patients. The second study was undertaken to understand the reasons, procedures, and perceptions of physician and nurse practitioner (NP) dispensing practice versus similar practices of nondispensers of legend and over-the-counter (OTC) drugs in the United States. The objective of the third study was to understand consumer perceptions of physician or NP dispensing of legend and OTC medications across the United States.

Methods

Study 1: Review of State Statute and Administrative Codes

State statute and administrative codes were reviewed to identify those states that permit prescribers to dispense medications to patients and any limitations on such practice. Statutory data were collected between October 2012 and January 2013. Seven databases were accessed to obtain the statutory and regulatory information. These databases included LexisNexis Academic, National Conference of State Legislatures—Issues and Research, National Association of Boards of Pharmacy (NABP) Survey of Pharmacy Law 2012,\textsuperscript{13} and Cornell Law School—Legal Information Institute. Searches were also conducted in PubMed, International Pharmaceutical Abstracts and the Cochrane Library. For each state, online versions of the statutory code (i.e., laws) and administrative code (i.e., regulations) were located. In particular, data mining efforts were focused on state laws and regulations relevant to health professionals. Search terms for state codes to identify relevant sections were \textit{physician, dentist, veterinarian, podiatrist, dispens*, practitioner, registration, label*, nurse practitioner, physician assistant, and non-pharmacist}. Websites for the National Board of Medical Examiners\textsuperscript{14} and NABP\textsuperscript{15} were used to identify individual state boards of medicine and pharmacy websites, respectively. There are limitations in the data obtained from legal resources. There is substantial lack of uniform terminology, and each state does not consistently use the same definitions. Codes may be drafted in prescriptive form, descriptive form, or combinations thereof. These writing styles introduce additional complexity to interpreting scope of authorization. Finally, laws and regulations change frequently, and current statutes and regulations, in particular jurisdictions, may not match the data presented.

Study 2: Physician and Nurse Practitioner Survey

Studies 2 and 3 were conducted in accordance with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guidelines for Good Clinical Practice and the Declaration of Helsinki, and they received approval from the University of Utah institutional review board.

Participants were 556 licensed physicians and 64 NPs from one of the following specialties: optometry, medical oncology or hematology-oncology, plastic or reconstructive surgery, dermatology, primary care (family medicine or general practice), internal medicine, or psychiatry who indicated that they had or had not dispensed a legend or OTC drug in the past 3 months. Participants were recruited from the WorldOne (www.worldone.com, New York, NY) and Universal Survey (www.universalsurvey.com, New York, NY) panels. Random electronic invitations were sent from September to
December 2012. The study was designed to recruit dispensers and nondispensers equally. Dispensing was defined as “having personally sold or given out medication, excluding medication samples.” The use of drug samples was explicitly excluded from the study. A total 1527 responded to the invitation and entered the survey, with 620 qualified to complete the final survey.

The survey assessed the level of dispensing among physician dispensers including dispensing frequency, drug categories dispensed, and the presence of pharmaceutical dispensing procedures by a 10-point Likert scale where applicable, as shown in Tables 1 and 2. Attitudinal questions addressed the perceived importance and burden of each dispensing procedure among dispensers. Physicians/NPs were asked whether their perceived cost of dispensed medications were higher, neutral, or lower compared with the costs from community pharmacies. General attitudes toward dispensing among dispensers and nondispensers were assessed with a 16-item statement battery. Future dispensing intent among dispensers and nondispensers was determined.

Study 3: Consumer Survey

Consumers were recruited from a separate, commercially available consumer panel operated by Toluna (www.toluna-group.com, Wilton, CT). Random invitations were sent out from September to December 2012. Prescription was defined for the consumer participants as “a medication requiring a prescription.” OTC was defined as “a medication you could purchase without a prescription.” The use of drug samples was explicitly excluded from the study. Minimum study quotas were set at 100 consumers 65 years or older, 300 without private insurance, and 750 who had purchased a prescription product from a physician or NP. A total of 9640 entered the survey with 1387 meeting the screening criteria. Of these, 388 were excluded due to incomplete or erroneous responses, for a final sample of 999 participants.

In the consumer survey, participants were asked if they had health insurance, whether medications were dispensed following a visit with their prescriber, and in what specialty area the prescriber practices. Patients were also asked about perceived medication costs, future purchasing practices over the next 2 years, experiencing an adverse drug reaction (ADR) when purchased from a physician or NP compared with a pharmacy, and the category of medication dispensed. If the consumer experienced an ADR, they were asked to identify who they consulted to provide medical information or management of the adverse effect. General attitudes toward medications purchased from a physician or NP were assessed with an 11-item statement battery, using a 10-point Likert scale shown in Table 3.

Statistical Analysis

Statistical analysis was conducted on the survey data only. The 10-point Likert scale items were considered to be continuous variables for analysis, and comparisons between dispensers and nondispensers were made using an independent sample t test. For comparisons of categorical outcomes, groups were compared using a χ² test, with separate categories of the outcome variable being further compared using a χ² decomposition approach when deemed appropriate. Significance was set at p<0.05.

Results

Study 1: Review of State Statute and Administrative Codes

Appendix 1 presents the references for sections of the statutory and regulatory codes. A total of 44 states authorize unrestricted dispensing by legally authorized prescribers, as shown in Figure 1A. Massachusetts, New Jersey, New York, and Texas allow prescriber dispensing of small quantities of medications from 72 hours to 30 days including controlled substances (i.e., Massachusetts only). Montana expressly prohibits dispensing activities by prescribers; however, the state creates a series of exceptions for unusual circumstances, such as rural locations that are geographically isolated from a pharmacy. Midlevel practitioners (i.e., NPs and physician assistants) are allowed to dispense within their respective scope of practice in 38 states, as shown in Figure 1B. Six states exclude midlevel practitioners from dispensing, and six states generally prohibit all nonpharmacist dispensing.

In 28 states, there is no requirement for nonpharmacist practitioners to register or notify licensing authorities of their intention to dispense medications (Figure 1C). In 16 states, nonpharmacist practitioners must register or notify their respective professional licensing board (e.g., medicine board, dental board,
Table 1. Dispensing Frequency, Perceived Cost Compared with a Pharmacy, and Future Intent Among Dispensing Prescribers

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Primary care</th>
<th>Internal medicine</th>
<th>Psychiatry</th>
<th>NP</th>
<th>Hematology/Oncology</th>
<th>Medical oncology</th>
<th>Plastic/Reconstructive surgery</th>
<th>Optometry</th>
<th>Dermatology</th>
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<td>65</td>
<td>56</td>
<td>53</td>
<td>49</td>
<td>59</td>
<td>46</td>
<td>44</td>
<td>31</td>
<td>57</td>
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<td>36</td>
<td>26</td>
<td>34</td>
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<td>41</td>
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<td>Once every 1–3 mo</td>
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<td>11</td>
<td>8</td>
<td>21</td>
<td>17</td>
<td>15</td>
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<td>The cost is higher than</td>
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<td>5</td>
<td>0</td>
<td>3</td>
<td>21</td>
<td>15</td>
<td>0</td>
<td>15</td>
<td>3</td>
<td>9</td>
<td>31.05</td>
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<td>in a pharmacy</td>
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<td>45</td>
<td>42</td>
<td>53</td>
<td>54</td>
<td>31</td>
<td>48</td>
<td>85</td>
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<td>31</td>
<td>20</td>
<td>28.34</td>
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<td>I will dispense to the same</td>
<td>60</td>
<td>50</td>
<td>69</td>
<td>52</td>
<td>49</td>
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<td>next 2 yrs</td>
<td>I will dispense to fewer patients</td>
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NP = nurse practitioner; NS = not significant.

*Statistically significant difference between groups (p<0.05).
podiatric medicine board, etc.) of their dispensing practice. However, nonpharmacist dispensers must register with the Nebraska Board of Pharmacy as a “delegated dispenser” and with the New Hampshire Board of Pharmacy as a “limited retail drug distributor.” A registration or formal notification process is required in 16 states, some of which require a separate registration form.

Compliance with pharmacy practice requirements for medication dispensing is required in 26 states (Figure 1D). Examples of compliance requirements include provision of labeling information, inventory control, and recordkeeping, among others. Eighteen states have no specific requirements for prescribers to comply with pharmacy dispensing requirements. Five states expressly require dispensing prescribers to abide by the same dispensing requirements for pharmacists.

Study 2: Physician and Nurse Practitioner Survey

The mean age of the physicians/NPs who completed the survey was 49.7 ± 2.5 years, with dispensers (48.5 ± 2.7) statistically younger than nondispensers (50.8 ± 2.5) (p<0.05). Respondents practiced for a mean of 18.2 ± 1.5 years (17.2 yrs for dispensers and 19.2 yrs for nondispensers). The total population was 82% white with a significant higher number of whites in the nondispenser group (86% nondispensers vs 79% dispensers; p<0.05). Additionally, approximately 16% of respondents were Asian, 10% Pacific Islander, 3–4%
Hispanic, and 1–2% African American in the dispenser and nondispenser groups. Survey respondents practiced in the following areas: optometry (17.9%), psychiatry (14.2%), dermatology (13.6%), plastic/reconstructive surgery (12.1%), hematology/oncology (11.3%), internal medicine (9.2%), primary care (7.2%), medical oncology (8.2%), and NPs (6.3%).

Among the 1527 prescribers who were screened, 62% reported having dispensed a medication in the past 90 days (Table 1). Half (52%) reported dispensing prescription medications every day, 32% weekly, and 16% every 1–3 months. The frequency was independent of the specialty group. Dispensing was more frequent among dermatologists. Dispensing behavior was independent of patient age or prescription insurance coverage. Only 8% of dispensing practitioners perceived the cost of medications to be higher than what patients would pay in a pharmacy, 45% equivalently priced, and 47% lower priced than in a pharmacy. These perceptions were associated with physician specialty groups ($\chi^2 = 31.05$, $p=0.013$). Twenty-four percentage of dispensing prescribers planned to increase the practice in the next 2 years, 60% reported planning no change in the proportion of drugs dispensed, and 16% reported to decrease their dispensing. Among nondispensing prescribers, 55% have never considered dispensing, 39% have considered dispensing but are yet to start the process, 2% have started the process but have not yet dispensed any medications, and 4% started but abandoned the practice.

Dispensing prescribers were significantly more likely to agree that dispensing improved patient adherence compared with the neutrality of nondispensing prescribers (Table 4). Dispensing prescribers were also significantly more likely to agree that “dispensing reduces the cost of health care to my patients and dispensing improves patient safety” compared with nondispensing prescribers. When asked to comment on the statement that “dispensing reduces the cost of health care to society,” dispensing physician/NPs were more likely to agree compared with nondispensing prescribers who are close to neutral.

Table 2 shows the dispensing frequency of legend/OTC medications categories. The highest dispensing rate of legend medications were for the central nervous system and dermatologic categories. In comparison, skin care and pain management products were the two most frequent OTC dispensed categories.
Table 3 lists the procedures in place for the management of dispensing practice. Proper drug storage (87%; mean importance rating 8.42 [scale 1–10]; mean burden rating 4.66 [scale 1–10]), patient counseling (86%; importance 8.35; burden 4.74), and maintaining prescription and drug recordkeeping (80%; importance 8.11; burden 5.71) are reported most frequently. Approximately 67% of dispensing prescribers have drug stock labeling and inventory control, 67% used system verification of product before dispensing, and 65% had prescription labeling in place with mean importance ratings of 7.53, 7.87, and 7.44 and mean burden ratings of 5.64, 5.09, and 5.38, respectively. Over half of dispensing prescribers have generic substitutions in place (59%, importance 6.56, burden 4.66) and medication profile/dispensing systems in place (53%, importance 6.81, burden 5.90). There is a statistically significant inverse relationship between a prescriber’s perceived importance of dispensing practice and his or her perceived burden ($r = -0.95, p=0.001$).

Study 3: Consumer Survey

The average patient consumer age was 46.6 ± 2.2 years. There was no significant difference in age between consumers who received their prescriptions from a dispensing prescriber versus a pharmacist. More than 15% were older than 65 years. Most patients (82%) were white, 10% were African American, and 7% were Asian or Hispanic. Most had private insurance (67.5%), and 76.4% had purchased a prescription product in the last year from a dispensing prescriber.

Two-thirds of patient consumers report purchasing their prescription medications primarily...
from a local pharmacy, local supermarket, or convenience store in the past year, with 14% of purchases made from a physician office or clinic. The remainder of consumers purchased their prescriptions by mail order (16%) or other outlets (4%). Primary care practitioners and internal medicine specialists were reported as the highest dispensing practitioners; these purchases were recurring, with a mean of three purchases in the past year. Of the prescription purchases, three-quarters were routine purchases; the remainder was emergency refills.

Overall, 7% of patients reported experiencing an ADR, which was the same among patients who received their prescriptions dispensed by a dispensing prescriber or pharmacist. Among patients who experienced a serious ADR while taking a prescription dispensed by a pharmacist, 42% consulted their primary care physician, 41% consulted a pharmacist, 15% went to urgent care or the emergency department, and 2% consulted another physician/NP. In contrast, when a prescription was purchased from a dispensing prescriber, 64% first consulted the physician/NP who sold them the prescription, 28% consulted a pharmacist, 6% went to urgent care or emergency departments (a 9% absolute decrease in urgent or emergent care usage as compared with pharmacist dispensing \(p<0.05\)), and 2% consulted another physician or NP.

Among patients purchasing prescription medications from a dispensing prescriber, 19% perceived the cost of a prescription to be higher than in a pharmacy, 58% about the same, and 23% less than in a pharmacy. A total of 63% of patients expected to purchase the same proportion of their medications from a physician/NP in the next 2 years. Seventeen percent of these prescription purchasers believed they would purchase more; 20% believed they would purchase fewer medications from this source.

In terms of attitudes, patients tended to moderately agree that dispensing by the prescriber “improves how safe it is for me to take the medication.” Patients were more neutral regarding the medication cost savings by prescriber dispensing, but 25% of customers were willing to pay more for the convenience. Only 24% requested that their physician or NP dispense directly to them, but 42% percent were pleased with the practice, feeling they received a higher level of care; 40% would like to purchase a broader range of medications. Interestingly, 64% of patients strongly agreed that “having a physician/NP and pharmacist both check my medication makes it safer for me to take the medication.” Half of patients strongly agreed that “I have a safer level of taking my medications when I can talk with my pharmacist about my medications.”

Discussion

These studies describe the legal authorization, frequency, driving forces, and patient perceptions regarding legally authorized prescriber dispensing across the United States. Overall, dispensing by a legally authorized prescriber is firmly entrenched in the U.S. health care system, although substantial interstate variation exists in the statutory and regulatory authorization. Prescriber dispensing appears driven by prescriber perceptions of better convenience and reductions in health care costs with patient agreement, and improved medication adherence without patient agreement. Overall, patients appear satisfied with the practice.

Prescriber dispensing has grown substantially since the late 1980s, becoming routine practice across many specialties.17, 18 Most legend medication categories are now currently dispensed, sustaining the growth in practice popularity. Patient consumers in the current study are supportive of the practice, based principally on two factors: convenience and lower perceived cost of health care. These findings suggest that the physician-patient relationship is strengthened through the provision of dispensing medications, a finding supported by previous studies.16, 18 Yet most patients remain committed to a system of physician/NP prescribing with pharmacist dispensing,19 a position also noted in our study. Despite growing capacity and patient support for prescriber dispensing, the bi-provider system of dispensing remains important, and perceived to be beneficial, in the minds of many patient consumers.

In preventing errors, the Swiss cheese model of human errors would suggest that a system consisting of physician/NP prescribing with pharmacist dispensing would reduce patient harm.20 However, the results of the current consumer study suggest that the rate of consulted ADRs (7%) was exactly the same with prescriber dispensing compared with pharmacist dispensing, with patients receiving their prescriptions from their physician/NP reporting fewer emergency department consultations. It is estimated that 0.6–1.7% of all emergency department visits are related to ADRs21–23 typically occurring in the
very young (i.e., 1–4 yrs) or the very old (i.e., older than 65 yrs), and more commonly in women.24 Therefore, patients presenting at the emergency department may cause an increased cost to the health care system. As this study's results suggest, a potential for reduced health care costs by reduced emergency department utilization exists; however, cost savings is multifactorial and economic analyses on the cost-effectiveness of prescriber dispensing are still needed. Additionally, actual costs or patient comorbidities were not included in this study. Furthermore, a prospective systematic comparison of reportable ADRs between dispensing prescribers and nondispensing prescribers (pharmacist dispensing) may help address patient safety concerns.

The present study was not directed at detecting direct ADR risk from prescriber dispensing in contrast to the bi-provider system of dispensing medications. The lack of consistent dispensing procedures by physicians/NPs (e.g., proper drug storage, patient counseling, drug purchase recordkeeping, system verification of product, prescription labeling, etc.), as noted in Table 3, may contribute to dispensing errors and ADRs, carrying the potential for enhanced physician or NP duty of care liability risk. In accordance with pharmacy case law, dispensing liability for drugs is generally considered to be a completely error-free standard; in other words, a no-mistake practice environment.25 With prescriber dispensing, it will be interesting to learn if the same error-free liability standard is applied by the courts to dispensing prescribers. Inconsistent dispensing procedures by dispensing prescribers may offer an opportunity for state medical and pharmacy boards and respective national organizations to collaborate on whether the current dispensing regulatory policies are in fact providing the intended patient protection or whether these regulations might be reframed to apply to all drug-dispensing professions without increasing adverse drug events and reducing liability risk.

There is much public policy dialogue about the blurring of scopes of practice among health care practitioners. Traditional paradigms allocate prescribing to legally authorized practitioners within their respective scope of practice, drug administration to nurses, and dispensing to pharmacists. The use of midlevel practitioners in the prescribing process as well as the involvement of pharmacists in more direct patient management, such as through medication therapy management or even pharmacist prescribing,26,27 tends to obscure the scope of practice definitions. It is clear from the results of these research studies that scope of practice of these professions is continuing to evolve.

**Conclusion**

Prescriber dispensing of legend and OTC drugs is firmly entrenched in the U.S. health care system, is likely to increase, does not appear to increase ADRs, and may reduce urgent care and emergency department visits. The reduction in urgent care and emergency department visits requires further study to confirm these preliminary findings.

**References**


Supporting Information
The following supporting information is available in the online version of this paper:

Appendix S1. Statutory and regulatory citations for legally authorized prescriber dispensing in the United States.