

Prescribers' and Organizational Leaders' Preferences for Education about Heavily Marketed Drugs

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Abstract

Objective: We conducted a study to assess the educational needs and interests of medication prescribers and organizational needs regarding heavily marketed drugs.

Study design: We used an Internet and paper-based educational needs assessment survey to gather data.

Methods: Approximately 1000 Denver-area Kaiser Permanente Colorado (KPCO) physicians, nurse practitioners, and physician assistants ("health maintenance organization [HMO] prescribers"); 780 Colorado Springs KPCO network (preferred provider organization [PPO] prescribers); and 36 Denver-area KPCO pharmacy leaders were surveyed. Prescribers were asked about interest in pharmaceutical development, approval, and marketing processes and interest in learning about accessing and using drug information in practice. They were also asked to identify areas in which they would like to improve prescribing practices. Organizational leaders were asked about areas in which curricula could assist current cost-effective prescribing efforts. HMO prescriber and leader surveys were conducted via the Internet. PPO learner surveys were conducted by mail.

Results: Responses were collected from 127 (13%) HMO and 70 (9%) PPO prescribers. Top interest areas in both groups were accessing unbiased drug information, comparing evidence about drugs within class, critical appraisal of drug information, off-label drug use, and addressing patient medication inquiries. Pharmaceutical industry marketing practices, roles and responsibilities of the US Food and Drug Administration, and the US drug development and approval process were rated lowest. HMO prescribers most wanted to improve prescribing for bacterial infections, depression, and diabetes; PPO prescribers also wanted to improve prescribing for migraine headaches. Highest organizational priority drug classes were those for depression and asthma.

Conclusions: Prescribers are interested in areas of pharmaceutical development and marketing that relate closely to providing patient care, especially in commonly seen clinical conditions. They are less interested in regulatory or policy aspects of the process.

Background

Pharmaceutical expenditures were responsible for 10% of all health care spending in the United States in 2004.¹ Medications are marketed by the pharmaceutical industry to prescribing clinicians and consumers. Contrary to published evidence, clinicians and students believe that they are not influenced by pharmaceutical industry marketing techniques.² Medication marketing can lead to increased prescribing (and presumably consumer use) of newer, often more expensive, medications.³ However, many newer agents do not offer therapeutic advantages over older agents. Given discrepancies between costs and quality of medical care in the US⁴ and given that yearly medical cost increases continue to outpace general inflation,⁵ pharmaceutical company marketing practices are receiving increased attention. From a health policy standpoint, it is appropriate to attempt to decrease prescribing of selected newer, heavily marketed medications that offer little therapeutic advance over existing medications.

The US Food and Drug Administration (FDA) works with pharmaceutical companies to de-

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termine labeled indications for prescription medication use. The FDA also regulates prescription marketing practices. Pharmaceutical companies are allowed to promote medications only for labeled indications, but off-label promotion occurs. Between 2001 and 2006, the FDA sent 190 warning letters to approximately 100 pharmaceutical companies about false or misleading advertising of more than 160 medications; 26 companies received repeat warnings about the same medication.⁶

In 1996, a consortium of 50 US attorneys general filed suit against Warner Lambert (now a division of Pfizer) alleging promotion of the antiepileptic drug Neurontin (gabapentin) for up to 12 off-label uses. In 2004, Pfizer paid \$430 million to settle civil and criminal Medicaid fraud and other claims.^{7,8} The attorney general earmarked a portion of settlement funds for grants to develop curricula to 1) educate health care professionals about the drug development and approval process; 2) increase health care professionals' awareness of, and ability to evaluate, pharmaceutical industry marketing techniques; and 3) provide strategies for accessing and evaluating drug information. The overall intent was to improve the cost-effectiveness of prescribing practices.⁹

Along with expert- and evidence-defined needs, assessment of needs from the prescriber's perspective helps prioritize learning objectives. This is especially important regarding marketing influence on prescribing practice, because clinicians often deny that an association exists; this topic might not be identified as a high priority unless it specifically addresses a perceived need. Additionally, given the rapidly expanding amount of medical knowledge

and limited available time for continuing education, clinicians must prioritize the educational topics they want to pursue. As one of 24 grantees in the Attorney General Prescriber Grant Program, we were concerned that a "predetermined curriculum" focusing on the US drug development and approval process and/or pharmaceutical industry marketing practices might not be appealing to prescribing clinicians. We therefore developed and conducted an educational needs assessment of clinician prescribers and organizational leaders to help guide development of curricular content. The needs assessment covered the pharmaceutical process from development to approval to marketing (both to clinicians and consumers) and the evaluation of available data to select pharmacotherapeutic options in practice. Development and results of this needs assessment are described here. Evaluation data on the extent to which the continuing medical education (CME) modules met their stated learning objectives, participant-intended and self-reported changes in prescribing practices, and data comparing prescribing

of heavily marketed medications before and after participation in the CME program will be available in the future.

Methods

Kaiser Permanente Colorado (KPCO) is a group-model health maintenance organization (HMO), consisting of the Kaiser Foundation Health Plan of Colorado and the Colorado Permanente Medical Group. KPCO has approximately 440,000 members in the Denver-Boulder, CO, metropolitan area. Additionally, KPCO operates a network model (preferred provider organization [PPO]) in the Colorado Springs and Pueblo, CO, metropolitan areas with approximately 45,000 additional members.

The multifaceted needs assessment for our curriculum sought primarily to identify self-perceived learning needs of prescribing clinicians (physicians, nurse practitioners, and physician assistants). It also sought the perceptions of KPCO pharmacy experts about areas where current cost-effectiveness prescribing initiatives could be assisted by our curriculum. Because

Contrary to published evidence, clinicians and students believe that they are not influenced by pharmaceutical industry marketing techniques.²

Table 1. Topics included in the learner needs assessments about the medication development, marketing, and approval process

• The US drug development and approval process
• Roles and responsibilities of the US Food and Drug Administration
• Pharmaceutical industry marketing practices
• Influence of pharmaceutical industry marketing practices on prescribing behaviors
• Role/influence of the pharmaceutical industry in CME
• Role/influence of the pharmaceutical industry in research
• Pros and cons of direct-to-consumer advertising
• Evaluation of pharmaceutical marketing claims
• Comparison of evidence for medications within specific drug classes
• Critical appraisal of drug information (eg, journal articles, CME or non-CME presentations, professional publications, advertising, pharmaceutical representatives, advice from "experts," etc)
• How to access unbiased drug information
• How to address patient inquiries about specific medications
• Identification of circumstances for off-label use of medications

CME = continuing medical education.

of differing exposure of clinicians in HMO versus PPO practices to pharmaceutical marketing (HMO clinicians do not see pharmaceutical representatives in their offices), we separately surveyed clinicians in both practice models. Using a six-point Likert scale (very interested to very disinterested), respondents

were asked to rate their interest in topics related to the pharmaceutical development, approval, and marketing process (Table 1). To help frame the curriculum in a context relevant to prescribers, we asked respondents to identify up to five classes of heavily marketed medications (Table 2) that most applied to their practices and to identify up to five medication classes for which they most wanted to improve prescribing.

At KPCO, clinical pharmacy specialists help coordinate efforts to improve the quality, safety, and cost-effectiveness of clinical prescribing. We therefore also developed an organizational needs assessment in an attempt to align our curricular efforts with organizational prescribing initiatives. The organizational needs assessment was distributed to clinical pharmacy specialists, pharmacy operations leaders, and chiefs of medical services. They were asked to indicate up to five classes of heavily marketed medications for which our curricular efforts could help narrow gaps between current and optimal prescribing or could complement organizational prescribing initiatives.

All needs assessments were initially conducted over the Internet, using SelectSurveyASP Advanced 8.1.10 (ClassApps.com, Overland Park, KS). The survey was conducted anonymously, but we requested information on respondents' academic degrees, specialties, and years in practice. As an incentive to participate, respondents including their names on their response were entered into a drawing for a \$25 gift certificate. Links to the needs assessments were e-mailed to prescribers; survey links were also placed on HMO and PPO Web site home pages. Because no Internet-based surveys were completed in

the initial PPO sample, we subsequently mailed hard copies with a fax-back option to PPO prescribers. One curricular topic area and three drug classes were inadvertently omitted from the PPO prescribers' hard-copy assessment. After preliminary analysis, we determined that the omitted drug areas were not likely to change the overall survey results, but the missing data on the curricular topic area was potentially consequential. We therefore mailed a follow-up one-question survey to the PPO sample, again with fax-back option, to assess interest and need in that curricular topic area.

Responses were imported from SelectSurveyASP or hand-entered into Excel (version 2003) spreadsheets (Microsoft, Redmond, WA) and imported into SAS 9.1 (SAS Institute Inc, Cary, NC) data sets for descriptive analysis. Responses are described separately for HMO and PPO prescribers. The study was approved by the Kaiser Permanente Colorado Institutional Review Board.

Results

Needs assessment invitations were sent to approximately 1000 HMO and 780 PPO prescribers. Responses were received from 127 (13%) HMO and 70 (9%) PPO prescribers, including 23 responses to the curricular area inadvertently omitted from the original survey (Table 3). On the basis of estimated sample size and return rate, preference of KPCO physicians was determined (95% confidence level) to within $\pm 4.1\%$ (Raosoft Sample Size calculator, www.raosoft.com/sample_size.html).

Compared with HMO responders, a greater percentage of PPO responders were physicians; PPO physician responders were in practice longer. Specialty areas of

Table 2. Categories of heavily marketed prescription medications included in the learner and organizational needs assessments

• Acne
• Acute coronary syndrome/myocardial infarction
• Attention-deficit hyperactivity disorder
• Allergy agent/antihistamine
• Alzheimer disease
• Anemia
• Arthritis/rheumatism
• Asthma
• Bacterial infections
• Benign prostate disease
• Bladder control
• Cancer
• Chronic bronchitis/emphysema
• Contraceptive/pregnancy prevention
• Depression
• Diabetes
• Dry eyes
• Erectile dysfunction
• Fungal infections
• Heart failure
• HIV agents
• Hypertension
• Insomnia
• Irritable bowel syndrome
• Lipid disorders
• Male-pattern baldness
• Menopause
• Migraine
• Obesity
• Osteoporosis
• Pain
• Parkinson's disease/restless legs syndrome
• Peptic ulcers/reflux
• Psychosis/mania (atypical antipsychotics)
• Sleepiness
• Smoking cessation
• Viral infections (non-HIV)
• Wrinkle control
• Other

respondents in both cohorts were similar, with proportionally fewer primary care and slightly more medical subspecialty responders compared with US physicians overall.¹⁰ Thirty-six clinical pharmacy

leaders and medical chiefs of service completed the organizational needs assessment.

Top interest areas among HMO respondents (percentage very or moderately interested) were: ac-

cessing unbiased drug information (92%), comparing evidence about drugs within classes (87%), critical appraisal of drug information (82%), off-label drug use (82%), and addressing patient medica-

Table 3. Characteristics of needs assessment respondents

Characteristic	Number (%) of Denver–Boulder HMO respondents (n = 127)	Number (%) of Colorado Springs–Pueblo PPO respondents (n = 70)	Number (%) of comparison group from the American Medical Association, 2006 ^a
Prescriber type			
Physician	67 (52.8)	61 (88.4)	
Nurse practitioner/physician assistant	49 (38.6)	2 (2.9)	
Did not indicate	10 (8.7)	6 (8.7)	
Prescriber specialty			
Primary care ^b	55 (43.3)	28 (41.2)	
Medical subspecialty	50 (39.3)	24 (35.3)	
Surgical subspecialty	22 (17.3)	16 (23.5)	
Years in practice			
<2	8 (6.3)	3 (3.1)	
2–5	15 (11.8)	8 (12.3)	
6–10	28 (22.1)	12 (18.5)	
11–20	34 (26.8)	18 (27.7)	
>20	42 (33.1)	25 (38.5)	
Years practicing as part of Kaiser Permanente HMO or PPO			
<2	20 (15.8)	11 (17.5)	
2–5	27 (21.3)	23 (36.5)	
6–10	28 (22.1)	22 (34.9)	
11–20	38 (30.0)	6 (9.5)	
>20	14 (11.0)	1 (1.6)	
Physician respondent characteristics ^c			
Primary care ^b	31 (46.3)	26 (43.3)	186,498 (53.2)
Medical subspecialty	23 (34.3)	18 (30.0)	72,794 (20.8)
Surgical subspecialty	13 (19.4)	16 (26.7)	91,182 (26.0)
Years in practice			
<2	4 (6.0)	1 (1.8)	
2–5	10 (14.9)	5 (8.8)	
6–10	16 (23.9)	10 (17.5)	
11–20	20 (29.9)	17 (29.8)	
>20	17 (25.4)	24 (42.1)	
Years practicing as part of Kaiser Permanente HMO or PPO			
<2	12 (17.9)	7 (12.7)	
2–5	16 (23.9)	19 (34.5)	
6–10	12 (17.9)	22 (40.0)	
11–20	20 (29.9)	6 (10.9)	
>20	7 (10.5)	1 (1.8)	

^aFrom Physician characteristics and distribution in the US: 2007 Edition.

^bFamily medicine, general internal medicine, general pediatrics.

^cThe percentage of primary care, medical subspecialty, and surgical subspecialty respondents in the Denver–Boulder HMO was similar to the overall distribution of physicians in the entire medical group (47% primary care, 21% medical subspecialty, 22% surgical subspecialty).

HMO = health maintenance organization; PPO = preferred provider organization.

tion inquiries (78%) (Figure 1). Pharmaceutical industry marketing practices, FDA roles and responsibilities, and the US drug development and approval process were the lowest-rated areas (44%, 38%, and 31%, respectively). Top interest areas among PPO respondents were similar: accessing unbiased drug information (84%), critical appraisal of drug information (81%), off-label drug use (80%), addressing patient medication inquiries (63%), and comparing within-drug-class evidence (61%). Pharmaceutical marketing practices (39%), FDA roles and responsibilities (23%), and the US drug development and approval process (19%) were the lowest rated areas in this cohort (Figure 1).

Three drug classes were mentioned as priority areas for improved prescribing in both cohorts. HMO respondents most wanted to im-

prove prescribing for bacterial infections (36%), depression (32%), and diabetes (27%). PPO respondents most wanted to improve prescribing for bacterial infections (27%), depression (19%), migraine (19%), and diabetes (17%) (Figure 2). There were differences, however, in ranking between cohorts in other areas. For example, despite being ranked third in the PPO cohort, migraine ranked 12th in the HMO cohort (17%); contraception ranked fourth in the HMO cohort (26%) but seventh in the PPO cohort (10%); bladder control ranked ninth in the HMO cohort (20%) but only 20th in the PPO cohort (7%). The highest-rated organizational priority drug classes (percentage of respondents indicating that including the drug class in the curriculum could assist current efforts making prescribing more cost effective) were for asthma (48%), depression (34%), and al-

lergy (28%); 24% of respondents included drugs for bacterial infections; 21%, for diabetes; and 14%, for migraine (Figure 3).

Discussion

Multifaceted needs assessment (assessment of learner self-identified needs; organizational leader needs based on practice gaps; and gaps in knowledge, competence, skills, and performance) is the expected norm under the new Accreditation Council for Continuing Medical Education criteria for accreditation.¹⁰ The results of our needs assessment showed that prescribers are interested in aspects of pharmaceutical development as well as the approval and marketing processes that directly relate to providing patient care. They were less interested in regulations, policy, and marketing techniques. Given the plethora of available continuing education opportunities and the

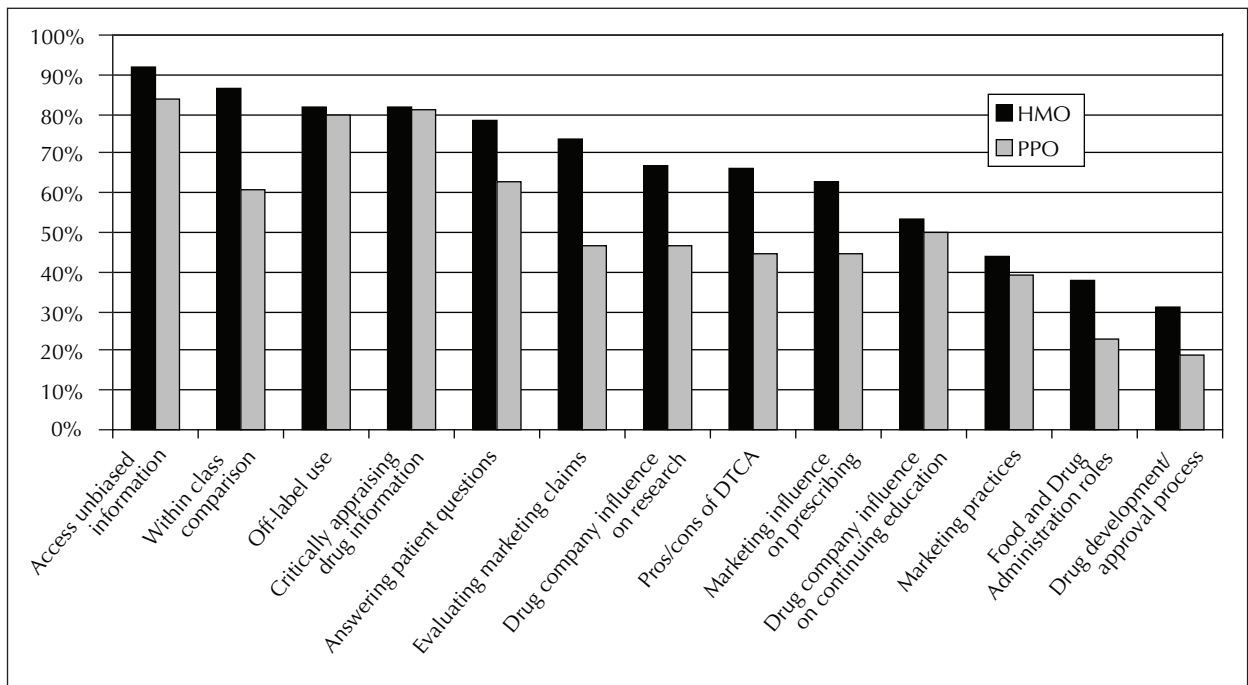


Figure 1. Curricular areas of interest among Denver–Boulder health maintenance organization (HMO) and Colorado Springs–Pueblo preferred provider organization (PPO) physicians, nurse practitioners, and physician's assistants. Percentages are of respondents who were "very interested" or "interested," as indicated on a six-point Likert scale. See Table 1 for full names of curricular topics.

DTCA = direct-to-consumer advertising.

need to maintain currency of medical knowledge, it is not surprising that clinicians would prioritize areas most directly applicable to their practices. However, a substantial minority of respondents did indicate interest in regulatory aspects of the process. Other items that could be added to future needs assessments include: 1) the role/influence of the pharmaceutical industry on FDA and governmental policy making and 2) the "orphan drug industry" (ie, why some drugs never come to market).

Prescribing clinicians indicated the desire to improve their prescribing for common conditions for which medications are heavily marketed, such as bacterial infection, depression, and diabetes, and/or for difficult-to-manage conditions such as depression and migraine headaches. These topic selections reflect not only the large proportion of respondents practicing in primary care settings but also that these conditions are common (or chronic) and potentially are treated by multiple prescriber types. There were similarities in the top-ranked areas of interest for improved prescribing in the HMO and PPO cohorts. (Bacterial infections, depression,

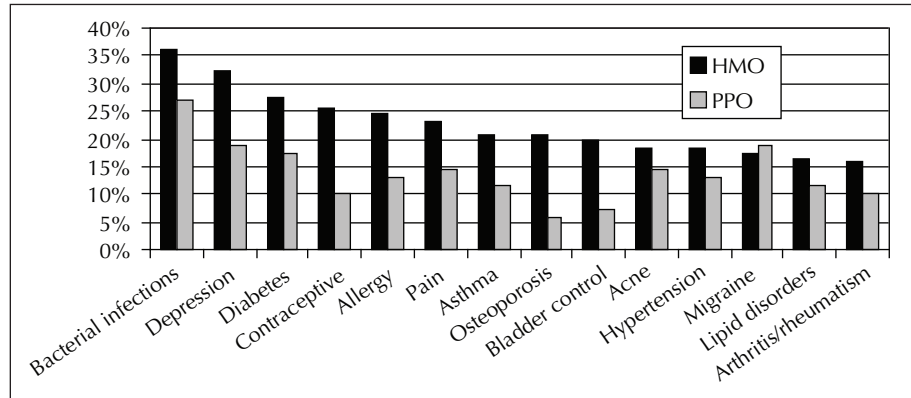


Figure 2. Selected drug class areas of interest (drug classes where at least 15% of either cohort indicated interest in improving prescribing) among Denver–Boulder health maintenance organization and Colorado Springs–Pueblo preferred provider organization physicians, nurse practitioners, and physician’s assistants. Percentages are of respondents who indicated drug class among the top five areas in which they would like to improve the cost-effectiveness of their prescribing.

HMO=health maintenance organization; PPO=preferred provider organization.

and diabetes ranked in the top four in each cohort.) However, there were differences in the percentage of respondents indicating interest in each category, and there were differences in rankings of other drug classes, such as those for migraine headaches, contraceptives, and bladder control. This may be due, in part, to differences in the response rate and sample size in the two cohorts. It may also be due to differing HMO and PPO formularies, access to clinical pharmacy specialists and exposure to target prescribing initia-

tives (more exposure in the HMO cohort), and differing exposure to pharmaceutical industry representatives (who are not allowed to make sales calls in HMO clinical offices). Despite this difference in exposure, however, we believe that these topics are relevant to clinicians practicing in group-model HMO, or other settings, “closed” to pharmaceutical company sales calls, because clinicians are still exposed to marketing at hospitals, at medical society meetings, in medical journals, and through mass media.

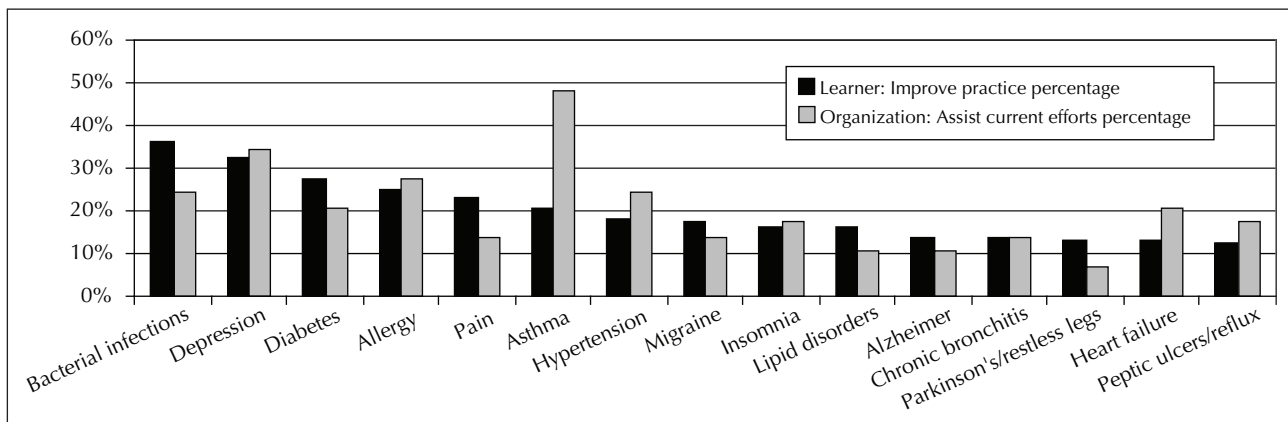


Figure 3. Comparison of drug classes by Denver–Boulder prescribing provider (learner) interest in improving practice and health maintenance organization responses that curriculum could assist current efforts in cost-effective prescribing. Percentages are of respondents who indicated drug class as being among the top five areas. See Table 2 for full listing of medication categories. Data are shown for only selected higher-rated medication classes.

Prescribing clinicians indicated the desire to improve their prescribing for common conditions for which medications are heavily marketed, such as bacterial infection, depression, and diabetes, and/or for difficult-to-manage conditions such as depression and migraine headaches.

The medication class preferences expressed on the organizational needs assessment align with ongoing KPCO initiatives. In some instances, the expressed preferences are driven primarily by quality-improvement efforts (eg, improving use of inhaled steroids in patients with asthma who frequently refill β -agonist prescriptions) rather than a response to decreasing use of heavily marketed medications. In other conditions, quality and cost-effectiveness both drive the organizational initiatives (eg, use of thiazide diuretics to treat hypertension).

The major limitation of this evaluation is the low response rate and possible self-selection bias to the needs assessment. Our final sample size was also too small to draw meaningful conclusions about differences between specialties and differences between physicians and nurse practitioners and physician's assistants. In our experience, however, response rates of 10% to 20% for broadly distributed educational needs assessment surveys are not unusual,^{11,12} and we believe we have an adequately representative sample for assessing potential learning needs and developing educational curricula of interest to a broad array of medication prescribers. The specialty distribution of Denver–Boulder respondents is similar to the specialty breakdown of all Denver–Boulder HMO physicians (Table 3, footnote c) and somewhat similar to specialty characteristics of US physician characteristics, although primary care physicians are slightly underrepresented in the latter comparison.¹³ Despite differences in practice arrangements between the HMO and PPO

prescriber cohorts (multispecialty group-model practice among the Denver–Boulder HMO prescribers, compared with small private practices among the Colorado Springs–Pueblo PPO prescribers), we noted similar interest in curricular topics and areas of desired prescribing improvement. These commonalities should make it possible to develop curricula on the pharmaceutical development, approval, marketing, and use process that appeal and apply to prescribing clinicians in multiple practice settings.

Conclusion

Educational programs for prescribing clinicians on pharmaceutical development, approval, and marketing should, to maintain relevance for busy clinicians, focus on aspects of the process closest to the issues that they face daily. Group- and network-model prescribers are similar in desired curricular topics and areas of desired prescribing improvement; curricula can be developed that meet the self-identified needs of both prescriber cohorts. Examples and case studies in areas of desired improvement in medication prescribing can help frame curricular content in relevant contexts for participants. To the extent possible, using medication classes where both learners desire to improve their prescribing and organizations have existing prescribing initiatives can create linkages and synergies between continuing-education and quality-improvement efforts.¹⁴

We believe that others can apply the methodology used to develop this curriculum (the needs assessment) to develop and tailor curricula on this topic to local settings. We believe that the methodology could be useful for single-specialty CME providers (ie, medical specialty

societies) or, with a large enough sample size, for multispecialty or multidisciplinary (physician, nurse, etc) CME providers. We further believe that our findings are relevant to medical schools, graduate and postgraduate medical educators, policy makers, hospitals, health care delivery systems, and others interested in funding, developing, and promulgating interventions to improve the cost-effectiveness of pharmaceutical prescribing. ❖

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Follow the Prescription

Sir Richard Nash was once asked by his physician
if he had followed his prescription.

"If I had," said Sir Richard,
"I should certain have broken my neck,
for I threw it out of my window."

— Benjamin Rush, 1745-1813, a Founding Father of the United States, physician, writer, educator, humanitarian. From Brieger G. *Medical American in the 19th Century: Readings from the Literature*. Baltimore (MD): The Johns Hopkins University Press; 1972