#### **CPNP POSITION PAPER**



## Improving medication-related outcomes for patients with psychiatric and neurologic disorders: Value of psychiatric pharmacists as part of the health care team

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#### Abstract

Psychiatric pharmacists have specialized knowledge, skills, and training or substantial experience working with patients with psychiatric or neurologic disorders. As part of the collaborative team with a physician, psychiatric pharmacists can provide comprehensive medication management (CMM), a direct patient care service, to patients with psychiatric or neurologic disorders. CMM is a standard of care in which all medications for an individual patient are assessed to determine appropriateness, effectiveness, safety, and adherence. Studies have shown that when psychiatric pharmacists are included as part of the collaborative team with a physician, medication-related outcomes for patients with psychiatric or neurologic disorders improve. Despite the evidence supporting the value of psychiatric pharmacists as part of the health care team, the very limited mechanisms for compensation for CMM limit the numbers of patients with psychiatric or neurologic disorders who have access to services provided by a psychiatric pharmacist. We believe that all patients with psychiatric or neurologic disorders should have access to CMM provided by a psychiatric pharmacist.

**Keywords:** psychiatric pharmacist, comprehensive medication management, medication-related outcomes, psychiatric disorder, neurological disorder, health care team

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#### **Purpose**

The purpose of this paper is to discuss the impact of psychiatric pharmacists and the ways in which they, as part of a collaborative team, can improve medicationrelated outcomes for patients with psychiatric or neurologic disorders. We describe the expertise and skills of psychiatric pharmacists and the associated positive outcomes for patients with these disorders. We also define comprehensive medication management (CMM) as the current practice model supported by the College of Psychiatric and Neurologic Pharmacists (CPNP). Finally, we outline barriers to the provision of services by psychiatric pharmacists and present action items aimed at effecting change.



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## Background

# Unmet Needs of Patients and Shortage of Providers

Providing care for persons with mental illness is a growing problem in the United States. Mental illnesses are often not properly diagnosed or treated. Approximately 43.7 million adults had a psychiatric disorder during 2012, an increase of almost 18% since 2008.<sup>1</sup> Additionally, data from 2012 suggest that approximately 4% of adults living in the United States experienced a serious mental illness (SMI) in that year.<sup>1</sup> Unfortunately, only 41% of US adults with any psychiatric disorder and 63% with SMI received mental health care.<sup>1</sup>

In the United States, mental health disorders are among the five most costly conditions to treat.<sup>2</sup> Expenditures have consistently increased, from \$35.2 billion in 1996 (adjusted for inflation) to \$57.5 billion in 2006.1,2 Medications make up a large percentage of the costs. For adults ages 18 to 64 years, the costs of medications for mental health or substance use disorders accounted for 51% of expenditures in 2007, for a total of approximately \$18.7 billion.<sup>1,3</sup> Although the demand for mental health care is growing, private- and public-sector payers have worked to reduce both the costs and the use of these services.<sup>4</sup> Between 2009 and 2011, states cut more than \$1.8 billion from their budgets for the provision of services to children and adults with mental illness, and this reduction has made it more difficult for patients to obtain needed mental health care.<sup>5</sup>

The lack of available health care services for the treatment of psychiatric and neurologic disorders is of grave concern, especially in light of the increasing demand for mental health care for chronic disorders, such as depression.<sup>4</sup> Untreated or undertreated psychiatric disorders are associated with lower educational attainment, higher societal costs for incarceration and public income support, and a larger number of medical complications requiring treatment.<sup>6,7</sup> Patients with depression are more likely than other patients to have comorbid medical illnesses, to be unemployed, and to have more job turnover and lost work productivity because of absences.<sup>8,9</sup> Additionally, those patients who can obtain mental health care may not be adequately treated. A study of patients with a history of depression found that 35% of those seeking treatment within the past year continued to have unmet needs, although 75% were given a prescription for a psychotropic medication.<sup>10</sup>

Pharmacotherapy is pivotal in treating patients with psychiatric disorders; however, its success is often limited by adverse effects, inadequate monitoring, and difficulties with adherence. In many cases, adverse effects go unrecognized. One study found that depressed outpatients report 20 times more adverse effects than their treating psychiatrists.<sup>11</sup> When adverse effects are not properly identified, the consequences can be dire. Nearly 90 000 visits by patients to the emergency room annually are due to adverse effects of psychiatric medication, most notably sedatives and hypnotics.<sup>12</sup> Depressed patients who report distressing adverse events associated with an antidepressant are significantly more likely to have a similar experience with a second antidepressant, even when the agent comes from another class of medications.<sup>13</sup> Antipsychotics and mood stabilizers can cause weight gain, hyperglycemia, and hyperlipidemia, thereby increasing the likelihood that chronic medical conditions, such as diabetes and cardiovascular disease, will develop.<sup>14-17</sup> However, patients may not receive the necessary treatment for these disease states once they develop. For many patients with schizophrenia, concurrent diabetes (30.2%), hypertension (62.4%), and hyperlipidemia (88%) remain undiagnosed and untreated despite the fact that patients are receiving medications known to increase the risk of metabolic syndrome.<sup>18</sup>

Although adherence problems are not unique to psychiatry, they can also significantly affect patient management and can inhibit recovery.<sup>19</sup> Estimates of nonadherence to psychotropic medications in the general population are reported to be 34.6% for antipsychotics, 34.7% for sedative-hypnotics, 38.1% for anxiolytics, 44.9% for mood stabilizers, and 45.9% for antidepressants.<sup>20</sup> Nonadherence rates for patients with SMI range from 23% to 50% for patients with bipolar disorder, schizoaffective disorder, or schizophrenia.<sup>21-23</sup> Patients with SMI who do not adhere to their medication regimens are more likely to attempt suicide, experience relapse, and require rehospitalization.<sup>22,24,25</sup> Medication nonadherence is the most common reason for rehospitalization for patients with schizophrenia; the second is lack of adequate response.<sup>26</sup> Psychiatric relapse is associated with a 2- to 5-fold increase in mental health care costs.<sup>27</sup> Treatment with and adherence to psychiatric medications also affect adherence rates to the medications used to treat other medical conditions. Patients with untreated or inadequately treated depression are three times less likely to adhere to medication regimens for other disease states, such as renal disease or cancer, or for organ transplantation.<sup>28</sup> Conversely, patients with HIV and depression are more likely to adhere to antiretroviral therapy when treated with antidepressants.<sup>29</sup>

Patients with psychiatric or neurologic disorders generally have other chronic medical conditions, making them sicker and more costly to treat independent of their mental health expenditures. A Maine Medicaid study found that a larger number of chronic medical conditions are associated with higher costs of care.<sup>30</sup> Furthermore,

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the mortality rates for patients with a psychiatric disorder such as schizophrenia are two to four times higher than those for the general population and have increased during the past three decades, a finding suggesting that patients with schizophrenia have not benefited from the improvements in care afforded to other patient populations.<sup>27,31</sup> In fact, life expectancy is 20% lower for patients with schizophrenia than for the general population.<sup>32</sup> Comorbid medical illnesses, such as cardiovascular disease, diabetes mellitus, hyperlipidemia, and hypertension, and lifestyle choices, such as cigarette smoking and lack of exercise, may play a role in declining health.<sup>27,32,33</sup> Patients with schizophrenia have a 2-fold higher risk of coronary heart disease and a 10-fold higher risk of suicide than the general population.<sup>32</sup> In general, patients with medical conditions and comorbid anxiety, depression, or both also have poorer outcomes. Anxiety and depression can be risk factors for the development of chronic heart disease.<sup>34–36</sup> A total of 31% to 45% of patients with coronary artery disease have comorbid depression, and these patients have a 2-fold higher risk of mortality than those without comorbid depression.37,38 The risk of depression is three times higher for patients with diabetes than for those without diabetes.<sup>39</sup> Patients with irritable bowel syndrome are also more likely than the general population to experience depression and anxiety, and depressed or anxious patients generally experience more severe gastrointestinal symptoms.<sup>36</sup> Asthma and pain are also associated with anxiety and depression.36,38 The Institute of Medicine recommends that if quality care is to be achieved, mental health services, including treatment for substance use disorders, must be integrated with primary care. Therefore, patient management, including cost-containment strategies, should target both psychiatric and neurologic disorders as well as medical illnesses, and should ideally occur in integrated practice settings.

Although patients with psychiatric or neurologic disorders have extensive unmet needs, the number of available clinicians has not kept up with the demand. In 2010, approximately 57% of psychiatrists were ages 55 years or older, whereas only 40% of all active physicians in the United States were this old.<sup>40</sup> Perhaps because of their age, the psychiatrists currently in practice are working less and are providing fewer patient care hours than in the past.<sup>4,41</sup> Between 2005 and 2010, some medical specialties experienced significant growth. For instance, internal medicine/pediatrics increased by 44%, and geriatric medicine expanded by 29%.4° During this same time period, the number of psychiatrists decreased by 0.7%.<sup>5</sup> In 2010 there were 38 289 active psychiatrists, or 1 for every 8072 people<sup>40</sup>; in contrast, there were 109 048 active internal medicine practitioners, or 1 for every 2834 people.

Even though psychiatry is currently the sixth largest medical specialty, many psychiatrists work exclusively in

inpatient or closed managed care settings.<sup>40</sup> This practice type limits access to care for patients with less severe psychiatric disorders, especially those patients who are uninsured. Many of these patients will seek mental health services through their primary care physician instead; 60% of patients with depression are treated in primary care settings.<sup>42</sup> Although primary care physicians may be able to provide some additional coverage, they are also in great demand and do not typically receive specialized training in psychiatric pharmacotherapy. Compared with psychiatric appointments, primary care appointments are generally allotted less time (13 minutes rather than 30 minutes), and primary care patients have more illnesses (6 rather than 1) that must be triaged and assessed.43 Consequently, the quality of management of psychiatric care in the primary care setting can be variable.

The shortage of psychiatrists is in sharp contrast to the mounting mental health care demands resulting from population increases, returning war veterans, improved and expanded medication options, direct-to-consumer advertising of psychiatric medications, and reductions in the stigma associated with mental health treatment.44,45 The most severe shortages traditionally occur in rural and economically disadvantaged communities.44,46 The 2010 Patient Protection and Affordable Care Act will provide insurance coverage for a large number of additional patients seeking mental health treatment in both primary care and specialty settings, and this increase in the number of patients may further exacerbate physician shortages throughout the United States. However, increased costs associated with participating in a psychiatric practice, combined with decreases in payments, increases in administrative time, and restrictive treatment protocols, may reduce psychiatrists' inclination to participate in private or public insurance programs.<sup>4</sup> Although 85% of psychiatrists surveyed in 2002 were accepting new patients, their willingness to do so was directly affected by the patient's health plan or ability to make payments.<sup>4</sup> Psychiatrists were more likely to accept Medicare than to accept private managed care plans or Medicaid. Limited acceptance of insurance may continue to reduce community treatment options despite the passage of the new health care law.

This shortage in mental health workers is a worldwide phenomenon.<sup>47</sup> One strategy for managing workforce shortages is the development of a strong team approach to patient management.<sup>7,42,48</sup> As experts in pharmaco-therapy with extensive training or experience in working with patients who have psychiatric or neurologic disorders, psychiatric pharmacists can help extend physician capacity and improve medication-related patient outcomes when they are integrated into treatment teams and can collaborate directly with physicians, patients, and other providers. Psychiatric pharmacists are specifically

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skilled in providing CMM services, which can be useful in identifying and correcting the medication-related problems that patients with psychiatric or neurologic disorders routinely face and that can lead to nonadherence to medication regimens.<sup>49</sup> Psychiatric pharmacists are uniquely trained to optimize patients' psychiatric and other medications, minimize adverse effects and drug-drug interactions, provide patient education, and reduce costs, all of which can help to enhance disease management, improve adherence, and empower the patient. As part of the psychiatric team or as the psychiatric specialist on a primary care or medical home team, psychiatric pharmacists can provide additional manpower or capacity for an overburdened system while substantially improving patient care and medication-related outcomes. Because of the specialized nature of their training and expertise, as described below, psychiatric pharmacists can add value to any health care team that provides treatment to patients with psychiatric or neurologic disorders.

## **Qualifications of Psychiatric Pharmacists**

Psychiatric pharmacists are qualified pharmacists who have specialized training in the area of psychiatric and neurologic disorders; this training enables them to provide direct patient care and to optimize medication therapy for patients with these disorders.<sup>19,50</sup> The American College of Clinical Pharmacy (ACCP) has defined the skills of a qualified pharmacist as proficiency in each of the following categories: clinical problem solving, judgment and decision making, communication and education, medical information evaluation and management, management of patient populations, and therapeutic knowledge.<sup>19,51</sup> Specialization in psychiatric pharmacy can be earned through postdoctoral residency training, equivalent clinical experience, or both.

Pharmacy degrees require the completion of at least 2 years of prerequisite undergraduate science courses and a 4-year professional Doctor of Pharmacy (PharmD) degree program accredited by the American Council on Pharmaceutical Education.<sup>52</sup> In 1997, the bachelor's degree was phased out, and all colleges and schools of pharmacy were required to implement a PharmD program. Students who want to pursue advanced clinical skills training and specialization can complete postgraduate year 1 (PGY-1) residency programs in pharmacy practice and PGY-2 residency programs in specialized clinical areas. Currently, there are approximately 50 PGY-2 specialty residency programs in psychiatric pharmacy in the United States.<sup>53,54</sup> Additionally, there are more than 10 psychiatric pharmacotherapy-related fellowships (usually 2-year programs) that have a research emphasis.<sup>55</sup>

Since 1992, psychiatric pharmacy has been recognized as

independent postlicensure specialty certification agency affiliated with the American Pharmacists Association.<sup>52</sup> Psychiatric pharmacists can be considered board eligible or board certified by the BPS. Pharmacists who earn this certification may use the designation of Board Certified Psychiatric Pharmacist (BCPP).<sup>51</sup> To be eligible to sit for the BCCP certification examination, a pharmacist must have (1) graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education or a qualifying program from a country other than the United States; (2) obtained a current or active license to practice pharmacy in the United States or another jurisdiction; and (3) completed 4 years of practice with at least 50% of the time spent in psychiatric pharmacy, or completed a PGY-1 residency plus 2 years of practice with at least 50% of the time spent in psychiatric pharmacy, or completed a specialty (PGY-2) residency in psychiatric pharmacy. Of note, completion of a general practice (PGY-1) residency is now a prerequisite for the completion of an accredited PGY-2 specialty residency. Psychiatric pharmacy activities have been defined in detail by BPS under the following key domains: patient management (eq, providing optimal medication therapy management for patients with psychiatric or neurologic disorders and other comorbid disease states), information management (eq, obtaining, generating, interpreting, and disseminating knowledge related to psychiatric pharmacy), and health policy and practice management (eg, collaboration with health care professionals, administrators, and the general public to promote the health, safety, and welfare of individuals and populations with psychiatric or neurologic disorders).<sup>56</sup> Each domain is further divided into specific tasks and knowledge requirements. For example, the patient management domain (64% of the board certification examination) requires specialized knowledge of psychiatric and neurologic disorders, including treatment and disease- and medication-specific monitoring parameters for psychiatric and neurologic disorders. It also requires the ability to recommend, initiate, and modify a pharmacotherapy plan. Currently, more than 750 pharmacists have earned the BCPP designation.<sup>57</sup> Once this designation has been earned, certification must be maintained by a rigorous requirement of 100 hours of BCPP recertification courses within a 7-year period or by reexamination every 7 years.<sup>58</sup> Through education, training, clinical experience, and lifelong learning, psychiatric pharmacists become experts in psychiatric pharmacotherapy and possess clinical skills that enable them to independently provide specialized direct patient care that promotes rational medication use.19,50

As is discussed in subsequent sections of this position paper, the contributions of psychiatric pharmacists have been well documented across a variety of health care settings. Pharmacists have a unique set of knowledge and skills that is ideal for providing comprehensive medication

management. Pharmacists are trained in pharmacology, pharmacokinetics, drug-drug and drug-disease state interactions, and optimization of medication adherence. Psychiatric pharmacists are also trained to demonstrate respect and compassion for patients with psychiatric illness and to effectively evaluate medication-related needs. Psychiatric pharmacists are positioned by this background and training to successfully engage patients in their treatment by providing information regarding the benefits of treatment and the expected adverse effects, thus empowering patients to participate in decision making.<sup>49</sup> Pharmacists are uniquely qualified to meet the unmet needs discussed above.

## Literature Review and Outcomes Summary

#### Methodology

Articles included in this review were found by a PubMed search for publications demonstrating the impact of psychiatric pharmacists in outpatient and inpatient settings. The citation lists in these articles were examined for additional studies not found by the initial search. We also reviewed a list, provided by CPNP, of publications discussing the contributions of the psychiatric pharmacist. Although some studies presented numerous types of interventions performed by psychiatric pharmacists and documented the positive perception of psychiatric pharmacists by the interprofessional team, studies that described only screening for psychiatric disorders (eg, depression) or that did not provide clinical outcomes data (eg, provided only descriptive data) were excluded from the summary.

#### **Results Overview**

We selected a total of 28 studies for this review (see Appendix). When evaluating the results of these studies, we found that psychiatric pharmacists have been providing clinical services and collaboratively working in interprofessional settings for more than 35 years. During this time, psychiatric pharmacists have been shown to provide a variety of benefits in both outpatient and inpatient settings. Although treatment was provided for various psychiatric and neurologic disorders, more than 50% of the studies focused primarily on depression. Other illnesses studied were anxiety disorders, posttraumatic stress disorder, schizophrenia, bipolar disorder, cognitive impairment (eg, Alzheimer disease, intellectual disability), and sleep disorders. The populations varied from adults to geriatric patients and spanned races and ethnicities, sexes, and income, thereby supporting the notion that psychiatric pharmacists practice in a wide range of clinical settings. Some of the clinical responsibilities and outcomes discussed included monitoring for efficacy via medication management (ie, initiating, decreasing, and increasing doses of pharmacotherapy), administering a wide array of psychiatric inventories and scales, increasing medication adherence, decreasing adverse effects, decreasing the number of primary care visits, providing cost savings, reducing the workload of psychiatrists, and improving patient satisfaction. Additionally, some of these studies examined the ability of psychiatric pharmacists to initiate and adjust the dosages of psychiatric medications under established formularies or collaborative practice agreements. Overall, the studies showed that mental health services provided by psychiatric pharmacists were perceived by other health care providers as a valuable and integral part of the treatment of patients.

### **Outpatient Setting**

Fifteen of the included studies were performed in outpatient settings (see Appendix). A total of 12 of these studies used a comparator group, 59-70 including 5 randomized controlled trials.<sup>59–63</sup> The other 7 studies were either nonrandomized  $(n = 3)^{68-70}$  or before-andafter comparisons of interventions (n = 4).<sup>64–67</sup> The randomized studies demonstrated favorable results. For example, in one study more than 500 patients were separated into two groups.<sup>59</sup> Approximately half of these patients were not taking antidepressants before the beginning of the study. After 6 months, patients in the intervention group (eg, pharmacists provided medication management or recommendations to primary care providers [PCPs] or provided patient education) had significantly higher rates of using antidepressant medications. The number of patients maintaining adherence was even higher when patients who initiated therapy during the study in the intervention group were compared with those in the control group (32% versus 11%; P = .001). There was also a greater improvement in modified Beck Depression Inventory scores for the intervention group than for the control group, but this difference did not reach statistical significance. Another study involving more than 100 patients evaluated the impact of psychiatric pharmacists in a health maintenance organization (HMO) setting.<sup>60</sup> As a result of intervention by the psychiatric pharmacists (eq, monitoring efficacy and adverse effects, managing medications according to a prescribing protocol), patients in the intervention group exhibited higher medication adherence rates (76% versus 60%; P = .057), higher patient satisfaction ratings (P = .023), and fewer primary care visits (15% versus 2%; P = .14) than the control group. Despite these positive results, the difference in clinical improvement between the two groups was not significantly different, possibly because of the small sample size. It is important to note that these results were based on returned surveys and that the response rate was much

lower for the control group. Selection bias may have occurred, because only those patients who returned the survey may have experienced greater benefits (eg, depressed patients may be less likely to complete and return materials).

A study in which pharmacists initiated telephone calls to patients who were following a guided medication education and monitoring protocol found improvements in patient knowledge (P < .05) and in adherence after 6 months (30% versus 49%; P < .05).<sup>62</sup> However, an intention-to-treat analysis found no significant differences between groups in adherence and overall improvement of clinical symptoms. Clinical outcome was determined by mailed forms, a method that may have affected the results because the sample size became smaller.

A 12-month study in which pharmacists provided interventions by telephone showed improvements in depressive symptoms, but the difference from the control group was not statistically significant.<sup>63</sup> There were no differences in the number of visits to PCPs, medication adherence, or patient satisfaction. It should be noted that the control group was encouraged to seek available resources, and these interventions may not have been adequately documented. Increases in adherence to medication regimens by patients with psychosis (eg, schizophrenia) or bipolar disorders were noted after 6 months.<sup>63</sup>

Seven trials ranging in duration from 2 to 36 months used a comparator group. Among these, 4 studies compared outcomes before and after an intervention<sup>64-67</sup> (eg, adjusting or prescribing medications, medication monitoring for efficacy or safety, medication education), and 3 trials were not randomized.<sup>68–70</sup> The before-and-after studies found statistically significant decreases in adverse effects (P < .005), <sup>64,66</sup> decreases in the number of medications prescribed  $(P < .005)_{1}^{64}$  decreases in the doses of antipsychotic drugs used (ie, 42% decrease in fluphenazine dose),<sup>66</sup> increases in patient knowledge,<sup>64</sup> and overall cost savings (more than \$22 ooo in one study 65 and approximately \$230 000 in another).<sup>66</sup> In some studies overall clinical improvements either were not measured<sup>65,66</sup> or did not prove to be statistically significant because of small sample sizes (ie, fewer than 25 patients).64,67

The 3 nonrandomized controlled trials provided positive and promising results.<sup>38–4°</sup> One retrospective study spanning 36 months compared psychiatric pharmacist services (ie, medication monitoring, occasional education) to psychiatrist services (ie, medication monitoring, psychiatric or medical examination, psychotherapy).<sup>7°</sup> Results of patient and caregiver assessments (Ellworth Personal Adjustment and Role Skills Scale of Community Adjustment) showed that the level of care provided by psychiatric pharmacists in monitoring, educating, and adjusting psychiatric medications according to the protocol was equal to that of psychiatrist services, and in some cases received higher satisfaction ratings. Most importantly, the study showed that psychiatric pharmacists could also decrease the workload of the psychiatrist, produce cost savings, and work with psychiatrists in providing a favorable level of care. A prospective controlled study evaluated psychiatric pharmacists' services (monitoring efficacy, adverse effects, and medication adherence) and gave psychiatric pharmacists prescribing privileges under protocol in an HMO setting.<sup>68</sup> During a 6-month period, patients in the intervention group had better medication adherence (P < .005), fewer PCP visits (P = .007), and higher patient satisfaction levels (P < .05). The clinical outcomes (eq, depression, functional impairment) improved significantly from baseline; however, these outcomes could not be compared with the control group because of the design of the study. Another study in which pharmacists in Australia provided patient education found that, despite improvements in depression, there was no difference between groups in medication adherence rates or improvements in clinical outcomes.<sup>69</sup> Limitations of the study include the provision by pharmacists of similar services to the control group and the enrollment of patients who were already taking antidepressant medications, factors that limited the effectiveness of the intervention. Overall, published reports suggest that including face-to-face interactions with patients who are initiating therapy may provide the best outcomes.

Three studies<sup>71–73</sup> did not use a comparator group but did measure clinical outcomes, including two studies<sup>71,73</sup> that provided economic analyses. In all three studies psychiatric pharmacists provided medication management, such as assessing patients for clinical efficacy and medication adverse effects, and providing patient education through face-to-face encounters (typically lasting 30-60 minutes). In two of these studies, the psychiatric pharmacist administered the scales or tests to measure clinical efficacy.<sup>71,72</sup> The first study, performed in a predominantly minority and low-income setting, found that symptoms of depression or anxiety improved by more than 50% (as measured by the Hamilton Rating Scale for Depression [HAM-D] or the Hamilton Rating Scale for Anxiety [HAM-A]) after approximately 6 weeks of antidepressant therapy.71 Patients also reported subjective findings of improved sleep (patients with insomnia) and management of symptoms related to cognitive impairment or dementia (eq, psychosis, decline in memory). Estimated cost savings were more than \$22 000 during a 15-month period. Another study in a low-income setting showed that the depression symptoms score (ie, Patient Health Questionnaire-9 [PHQ-9]) improved by 5.7 points (P=.02) and that more than 75% of treated patients had improvements in Clinical Global Impression Improvement (CGI-I) scores.<sup>72</sup> In the third study, in which pharmacists worked under a prescribing protocol, the 48 patients enrolled in the program showed overall improvements in depressive symptoms (ie, PHQ-9 scores improved by 6.2 points; P < .0001), and cost savings were estimated to be more than \$40 000 per year.<sup>73</sup>

Several lessons can be learned from these outpatient trials. When working alongside PCPs and psychiatrists, psychiatric pharmacists can increase rates of medication adherence, improve patient satisfaction, increase patient knowledge regarding pharmacotherapy, and monitor medication efficacy and adverse events. These results are promising and have demonstrated improved clinical outcomes (eg, improved effectiveness, fewer adverse effects) and cost-effectiveness. However, the limitations of published studies, such as small sample sizes, the inability to properly assess the control group, and the inclusion of patients who may have already been receiving pharmacy services (thus limiting the measurement of clinical improvement) make it difficult to determine differences in clinical improvement between intervention and control groups. Even though these studies have some limitations, however, they support the conclusion that psychiatric pharmacists are an integral part of the interprofessional team. Future trials should evaluate face-to-face interventions, which may provide even greater clinical efficacy. The lack of office space or transportation, and inclement weather at visit times can act as barriers. Future studies examining the impact of all health care providers, not just pharmacists, should evaluate the use of computers or tablets (eg, Skype) to engage patients with limited access. The use of mobile devices (eq, texting, apps) may also be useful, especially with young adults who may suffer from depression but are more technologically savvy. Overall, the use of technology should be considered, whenever appropriate, for engaging patients.

## **Inpatient Setting**

In addition to providing services in the outpatient setting, psychiatric pharmacists participate in numerous clinical activities in inpatient settings, and these activities directly contribute to the improvement of care for patients with psychiatric or neurologic disorders (see Appendix). Inpatient psychiatric pharmacists are involved in activities such as multidisciplinary team rounds, reconciliation of admission or discharge medications, and patient discharge education.<sup>74</sup> Psychiatric pharmacists engage in patient interviews, review patients' medical records, and complete analyses of medication use in an effort to provide oral and written recommendations on behalf of patients.<sup>75</sup> Clinical pharmacy interventions also take the form of

initiating psychiatric pharmacotherapy according to established protocols.<sup>76</sup> Some of the earliest published reports describing psychiatric pharmacists' services in mental health facilities show that these services included presenting unbiased and valuable drug information to medical staff and serving on the Institutional Review Board, the pharmacy and therapeutics committee, or other institutional committees.<sup>77</sup>

Inpatient psychiatric pharmacists have improved the use of medications for vulnerable patient populations that are particularly sensitive to the effects of psychiatric medications, such as children,<sup>78,79</sup> the elderly,<sup>75,80</sup> and those with an intellectual disability.<sup>81–84</sup> One published study found that psychiatric pharmacist consultation contributed to a reduction in the inappropriate use of several psychiatric medication classes, including antipsychotics (P < .001).<sup>82</sup>

A prospective cohort outcomes study undertaken in a state psychiatric inpatient facility assessed the impact of specific psychiatric pharmacy services. Services included attending treatment team meetings, performing baseline assessments and weekly reviews, providing pharmacotherapy recommendations, obtaining medication histories, reviewing medication administration records daily, monitoring for adverse drug reactions, conducting medication education classes, and educating patients before discharge.<sup>85</sup> Results indicated that, compared with control participants (n = 48), patients with moderate SMI who received intensive psychiatric pharmacy services (n = 45) exhibited significant improvements in clinical response as indicated by scores on the Brief Psychiatric Rating Scale (BPRS), CGI, and HAM-D (P < .001). Additionally, medication-induced extrapyramidal symptoms decreased significantly, as measured by the Abnormal Involuntary Movement Scale (P=.024), the Barnes Rating Scale for Drug-Induced Akathisia (P = .042), and the Simpson-Angus Rating Scale for Drug-Induced Extrapyramidal Symptoms (P = .002). The patients were highly satisfied with the pharmacy services they received. This study demonstrated that a comprehensive and integrated patient-focused approach by the psychiatric pharmacist can lead to improvements in managing adverse drug reactions and optimizing the overall use of psychiatric medication.

A study performed in a 40-bed mental health facility found that certified pharmacist prescribers (those who have completed additional clinical psychiatric training) prescribed medications to psychiatric inpatients as appropriately as physicians did.<sup>86</sup> In fact, the independent evaluators (2 psychiatrists and 2 psychiatric pharmacists) judged that certified pharmacists' prescription orders were more appropriate than physicians' orders. Statistically significant differences were noted between the scores of certified pharmacist prescribers and those of physicians in overall prescribing of psychiatric medications (ie, antipsychotics, anticholinergics, antidepressants; P < .001). Although the results do not address clinical significance or long-term outcomes, certified pharmacists' prescribing was found to be just as safe and appropriate as physicians' prescribing. As a result of obtaining prescribing privileges, psychiatric pharmacists, in collaboration with psychiatrists and other members of the psychiatric staff, provided relief to psychiatrists' heavy workloads,<sup>87</sup> thereby apparently improving the overall demands of an inpatient psychiatric work setting and meeting the needs of patients.

Psychiatric pharmacists' prescribing under a collaborative agreement with a physician also leads to improvement in patients' hospitalization rates. The length of stay for patients with schizophrenia managed by a psychiatric pharmacist was 24% shorter than that for patients with schizophrenia managed by a psychiatrist, although this difference was not statistically significant.<sup>88</sup> Readmission rates to the same hospital within a period of 1 year after discharge were significantly lower for the patients managed by a psychiatric pharmacist (P < .05). This finding is particularly interesting because new US policy core measures by the Centers for Medicare & Medicaid Services (CMS) limit reimbursements for patients with certain illnesses (eg, acute myocardial infarction, heart failure, pneumonia) who are readmitted within 30 days.

A variety of inpatient psychiatric pharmacy interventions in psychiatric hospitals can lead to cost savings. A cost analysis evaluated 2220 interventions applied to patient care during a period of 18 months, including clarifying medication orders, identifying medication administration record discrepancies, and recommending dosing adjustments.<sup>89</sup> The study found that psychiatric pharmacists' interventions not only optimized patient care but also led to substantial cost savings of \$125 500 for the psychiatric institution.

One area in which psychiatric pharmacists have an impact in the inpatient setting deserves greater attention: the skill of disseminating drug information to other members of the multidisciplinary team. Education about the appropriate use of psychiatric medication in the inpatient setting can change the frequency of medication administration and improve the rational use of psychiatric medications.<sup>90</sup> A study of the impact of psychopharmacology review by the psychiatric pharmacist demonstrated that a systematic approach in teaching such material to psychiatry residents and staff psychiatrists resulted in the evidence-based use of psychiatric medications.<sup>90</sup> These findings demonstrate that very little formal instruction in clinical pharmacology is provided to medical doctors throughout clinical practice. Adding a psychiatric pharmacist to the medical team allows for ongoing dissemination of important pharmacologic information that supplements clinical experience.

The value of expanded roles for psychiatric pharmacists has been well defined in both outpatient and inpatient settings.<sup>91</sup> Other psychiatric health care professionals have a good understanding of the extended clinical roles of psychiatric pharmacists and have a positive perception of contemporary pharmacy practice.<sup>92</sup> The continually evolving role of psychiatric pharmacists in inpatient settings presents an opportunity to move closer to the goal of patient-centered care as advocated by the Institute of Medicine.

## **Current Practice Models**

#### **Comprehensive Medication Management**

In 2012, the Patient-Centered Primary Care Collaborative (PCPCC) developed guidelines for CMM to ensure that each medication, including nonpsychiatric medications, is individually assessed to determine its appropriateness for the individual patient. Acting as a member of the health care team, psychiatric pharmacists meet individually with the patient to determine whether each medication is effective for the medical condition and is safe given the patient's comorbid conditions and other medications. They ensure that the patient can adhere to the regimen as intended, and they monitor the patient for any adverse effects.93 CMM is a distinct service from Medication Therapy Management (MTM), which was adopted in 2003 by CMS and must by law be offered to high-risk patients enrolled in Medicare Part D plans. The main difference between the two services is that CMM is a well-defined, patient-centered care practice under which the pharmacist provides direct patient care services as a member of the health care team, not as an independent practitioner. Another major distinction between MTM and CMM is that CMM is an ongoing service, rather than a one-time intervention, which allows patients to develop a relationship with their pharmacists. There are similarities between CMM and the core elements of MTM, as described by the American Pharmaceutical Association and the National Association of Chain Drug Stores Foundation, including creation of a personal medication record, identification and resolution of medication-therapy problems, provision of referrals as needed, documentation, and follow-up.94,95 However, because CMS did not specifically define what constitutes MTM, there are many variations, as determined by individual Medicare Part D plans. CPNP has endorsed CMM because it is a clearly defined, evidencebased model for ongoing direct patient care provided by pharmacists, and it focuses on the pharmacist as an integrated part of a treatment team rather than as an independent provider.96

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According to CPNP and the Patient-Centered Primary Care Collaborative, CMM should be interactive with the patient, preferably with a face-to-face assessment of patient needs, and should occur separately from any dispensing or administrative duties. CMM must include making an assessment; forming, communicating, and helping to administer a care plan; and ensuring appropriate follow-up and documentation as an integral part of a treatment team. The assessment should include the patient's complete current medication use and experience, including beliefs, benefits, and adverse effects associated with medications. During the assessment, the psychiatric pharmacist should develop a complete medication list for the patient, identifying all medications taken, including prescribed and over-the-counter medications, vitamins, and supplements. The assessment should also include the use of illicit substances, alcohol, tobacco, and caffeine, as well as a record of any preventative therapies, such as immunizations. The psychiatric pharmacist then interprets clinical data, including vital signs, laboratory values, and rating scales, to ensure that each medication is appropriate, safe, and effective in meeting the patient's goals for therapy. CMM also addresses the crucial element of adherence. As the medication expert, the psychiatric pharmacist develops a treatment plan to resolve any medication-related problems, communicates interventions to the patient and the treatment team, and documents the interventions in the medical record. Finally, the patient is scheduled for routine follow-up so that the psychiatric pharmacist can assess and document the outcomes of any changes that were made. Repeat visits should occur whenever the patient's health status changes and at transitions of care.93

Patients who may benefit most from CMM include those who are undergoing a transition in care (admission or discharge from a hospital or nursing home), taking multiple chronic medications, suffering from chronic diseases, being seen by multiple providers, taking medications that require frequent monitoring (eq, clozapine, lithium, antipsychotics), or exhibiting poor medication adherence.<sup>94</sup> For example, patients who are admitted to or discharged from the hospital are at higher risk of an adverse drug event (ADE). An evaluation of 4108 admissions at a tertiary teaching hospital found 247 ADEs and preventable drug events, which were associated with a mean increase in length of stay of 4.6 days.<sup>97</sup> The authors estimated that, at that hospital, the annual cost of all ADEs was \$5.6 million and the annual cost of preventable ADEs was \$2.8 million. As many as 20% of patients may have an adverse event after discharge, and adverse medication events are the most preventable type.<sup>98</sup> By focusing on these transition points of care, pharmacists working in inpatient hospitals and performing CMM can help to reduce costs to the patient and the institution. In a medical home model, patients

who received medication management services at discharge had lower readmission rates than other patients at 7, 14, and 30 days after discharge; these lower rates translated to a cost savings of \$1.5 million annually.<sup>99</sup> This finding is important because future reimbursements are likely to trend away from a fee-for-service model and toward a pay-for-performance model; such a change would offer an incentive for reductions in the number of admissions and the high-intensity use of resources such as emergency departments and urgent care centers.<sup>100</sup> By providing CMM, psychiatric pharmacists can work with and develop relationships with these high-risk patients who may otherwise use emergency services for their care.<sup>101</sup>

#### **Examples of Current Practice Models**

Through the support of a state grant, a psychiatric medication management private practice group in Montana provided CMM for patients with psychiatric or neurologic disorders, including depression, anxiety, and bipolar disorder. Data demonstrated cost savings of \$586 per patient, a 2.8:1 return on investment, and favorable patient outcomes, such as improvement in clinical status and patient satisfaction.<sup>102</sup> Other psychiatric pharmacy CMM practice models, including Kaiser Permanente– Colorado and Genoa Health Care, have been previously described in the commentary on "Psychiatric Pharmacist Integration Into the Medical Home," which was published in the *Primary Care Companion* in 2013.<sup>49</sup>

Few published studies have evaluated the outcomes achieved by CMM for patients with psychiatric or neurologic disorders. Psychiatric patients have multiple medical comorbid conditions, including metabolic effects that may benefit from medication management. Several studies have shown that patients, physicians, other providers, and institutions can benefit from CMM in both the primary care setting and the medical home model.<sup>102</sup> It should be noted that in some of the studies discussed below, the authors may have used the term MTM, although the actual services provided meet the criteria of CMM. To remain consistent with the original publications, this review will use the authors' terminology to describe the service.

Fairview Health Services of Minneapolis–St Paul is a nonprofit health care system at which more than 2.7 million patients are seen annually. A 1-year prospective study of medication management services was performed from August 2001 to July 2002 at 6 clinics in this system. This study found that 637 medication therapy problems were resolved by 285 interventions. Medication management services were provided by pharmacists in conjunction with PCPs. Patient outcomes from 6 outpatient clinics offering medication management services (the intervention

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tion group) were compared with patient outcomes from 1 of 9 Fairview clinics that did not offer such services. The percentage of patients who met the goals of therapy was higher in the intervention group than in the control group for hypertension (71% versus 59%) and cholesterol management (52% versus 30%). Total health expenditures declined from \$11965 to \$8197 per person (n=186, P < .0001). The reduction in total annual health expenditures exceeded the cost of providing CMM services by more than 12:1.<sup>103</sup>

During the past several years, Fairview's care model innovation (CMI) initiative was organized to decrease reliance on fee-for-service payment systems. To accomplish this goal, CMI clinics relied on team-based care, and the Fairview system was categorized as a level 2 Accountable Care Organization. Treatment teams consisted of PCPs, pharmacists, nurses, certified diabetes educators, dietitians, and health coaches. Pharmacists' roles on the treatment team included face-to-face medication therapy management consultations, home visits, telephone visits, telehealth (Internet-based video) visits, and covisits with other providers on the team. They also developed collaborative practice agreements allowing them to help manage medication therapy for patients with diabetes and other chronic conditions. In 2008, outcomes from the 4 CMI team-based outpatient clinics were compared with outcomes from the other 38 non-CMI clinics. From December 2008 to March 2010, per-patient per-month spending increased by 3.7% in the team-based CMI group but by 14.7% in the standard clinics. A total of 40% of patients with diabetes met all 5 benchmark care goals in the team-based clinics, whereas only 17.5% of patients with diabetes met these goals statewide. Pharmacists provided CMM services for 823 patients in the CMI clinics during that period, with an average of 2.13 visits per patient. Pharmacists were able to resolve a total of 4135 drug therapy problems, more than 2 per visit.<sup>104</sup> This finding is important, because patients with psychiatric and neuropsychiatric disorders often have chronic medical conditions, such as hypertension and hyperlipidemia, and would therefore benefit from services such as those provided by a psychiatric pharmacist who is familiar with both the patient's psychiatric or neurologic disorders and the patient's other medical comorbid conditions.

In a 1-year pilot project carried out in 2009 and 2010, pharmacists in Connecticut initiated a pharmacist network to contract independently for medication management services. The pharmacists met individually with patients and provided medication management services at 4 health centers in Connecticut. Pharmacists had access to the patients, their electronic health record, and pharmacy claims data. For 88 patients with chronic disorders, including pain, lipid disorders, hypertension, asthma, chronic obstructive pulmonary disease, diabetes, and depression, the pharmacists documented 3248 medication discrepancies between data sources. Of these, 917 constituted medication therapy problems, and only 26% of these problems were attributed to a lack of adherence to medication regimens. Most of the problems involved the need for an additional medication (30%), an adverse medication event (16%), the need to switch medications (7%), the need to discontinue an unnecessary medication (7%), an ineffective dose (7%), or the need to reduce a potentially toxic dose (5%). Pharmacist interventions resulted in estimated annual savings of \$1123 per patient in medication claims and \$472 per patient in medical, hospital, and emergency department expenses. The estimated total savings were approximately 2.5 times the cost of the fees for the pharmacists and network administration.<sup>105</sup>

At the University of California, San Diego, 2 boardcertified psychiatric pharmacists initiated a collaborative medication management clinic with psychiatrists in the outpatient psychiatric service. The clinic provided a full range of outpatient services for patients with SMI, including major depressive disorder, schizophrenia, schizoaffective disorder, and bipolar disorder. Psychiatric pharmacists were assigned to work with a supervising attending physician, with whom they met at least bimonthly to discuss patient progress. An annual performance review was also conducted to assess the competency of the pharmacist. Pharmacists served on a multidisciplinary team and saw patients 3 days per week. Clinical activities included taking vital signs, conducting metabolic and psychiatric assessments, assessing for adverse events, providing patient education, and making medication-related interventions. Rating scales used included the CGI, the Abnormal Involuntary Movement Scale, the Drug Attitude Inventory, and the Milestones of Recovery Scale. Laboratory values monitored included fasting glucose, fasting lipid panel, complete blood counts, serum chemistry, liver enzymes, and drug levels. Pharmacists also administered depot injections of antipsychotics and made referrals to other counseling services as needed. They documented activities in the patient's medical record, and each documentation was cosigned by the assigned attending physician. Psychiatric pharmacists comanaged 68 patients during a 1-year period. Under a scope of practice, they initiated medications such as antidepressants, antipsychotics, and mood stabilizers. The clinical condition of 56 patients (82.3%) comanaged by the pharmacists remained stable; 12 patients were lost to follow-up (10 lost contact, 1 moved away, and 1 died of natural causes). Pharmacists spent an average of 26 minutes per patient visit, with a mean total contact time of 174 minutes per patient. Psychiatrists at the clinic gained interest in this practice model, and this small pilot study led to increases in the involvement of psychiatric pharmacists over time.<sup>106</sup>

In 2007, the Veterans Health Administration began a joint initiative between the Veterans Affairs (VA) Offices of Mental Health Services and Primary Care Services. The goal was to integrate evidence-based mental health services into the primary care setting under the Patient Aligned Care Team model.<sup>107</sup> This initiative focused on the 7 foundational principles of (1) creating patient-driven services; (2) offering team-based care; (3) increasing the efficiency of care; (4) providing comprehensive care, including access to specialists; (5) developing continuous service across time; (6) improving communication; and (7) developing seamless coordination of care. Pharmacists served on care teams, and patients were referred to them for specialty services, including CMM.<sup>108</sup> In 2013, approximately 2640 pharmacists were working in the VA system under advanced scopes of practice, as members of a clinical treatment team and with prescribing privileges. These pharmacists have been working as nonphysician providers in nearly 40 subspecialty settings, including pain management and mental health. The value that clinical pharmacists can provide has been recognized, and the role of the clinical pharmacist in the VA system is being standardized. During a 6-month period from April to September, more than 35 000 pharmacy interventions were made and documented by pharmacists across 9 pilot sites. This initiative will continue to be deployed across the country as pharmacists, including psychiatric pharmacists, continue to bridge the gap between primary care and specialty care.<sup>109</sup>

Whether in a primary care or a mental health setting, patients can benefit from psychiatric pharmacists' expertise in pharmacotherapy and their experience in educating patients about the risks and benefits of treatment.49 In fact, if the patient is to be treated as a whole person, primary care and mental health outcomes cannot be divided into separate domains. Integrated care requires the recognition that the use of psychiatric medications, such as antidepressants and antipsychotics, can result in other medical problems. In addition, patients with severe mental illness may be at a higher risk of cardiovascular problems regardless of whether medication is prescribed.<sup>110</sup> Because of their specialized training in pharmacology, pharmacokinetics, and drug-drug and drug-disease interactions, psychiatric pharmacists are well positioned to partner, as a member of the health care team, with patients, families, nurses, social workers, and PCPs or psychiatrists, and to identify medication-related problems, increase the number of patients who can be treated, and optimize care.49

## Challenges

As demonstrated in the studies and practice models described above, psychiatric pharmacists can have a

positive impact on medication-related outcomes for patients with various psychiatric or neurologic disorders across multiple practice settings. Numerous studies have demonstrated substantial increases in clinical (therapeutic and safety), humanistic, and economic outcomes when psychiatric pharmacists are part of the care of patients. There are multiple examples of practice models in which psychiatric pharmacists are involved with direct patient care as part of the multidisciplinary team. Psychiatric pharmacists, working as part of a team of health care providers, can improve patient outcomes and reduce costs. Additionally, adding a psychiatric pharmacist to the team allows increases in the number of patients that physicians can see in a practice or in a patient-centered medical home (PCMH). Results from studies of current practice models that include elements of CMM have demonstrated that more patients meet treatment goals and that total health care costs are lower when pharmacists provide care as part of the team. Despite initial evidence demonstrating positive outcomes such as those mentioned above, there remain barriers that must be addressed if all patients are to have access to a psychiatric pharmacist as part of the health care team.

#### **Engaging Other Professional Organizations**

The American Medical Association (AMA) has been one of the most vocal organizations in favor of limiting, rather than expanding, the scope of practice for pharmacists and other health care providers. In recent years, the AMA has passed several resolutions opposing legislation that would have allowed pharmacists to play a greater role in direct patient care.<sup>111,112</sup> For example, when the US Food and Drug Administration was considering creating a third class of medications whose appropriateness was to be determined by pharmacists, the AMA opposed it. The AMA also stated that pharmacists who ask questions to verify the legitimacy of prescriptions for controlled medications before they are dispensed "are interfering with the practice of medicine."<sup>113</sup> In 2012 the American Academy of Family Physicians (AAFP) revised its position statement regarding the role of pharmacists; this statement reflects support for collaborative practice agreements and for the role of the pharmacist as a member of a health care team coordinated by the family physician.<sup>114</sup> However, similar to the position held by the AMA, the AAFP's revised position statement expressed concern regarding fragmentation of care if collaboration between the physician and the pharmacist does not occur.

The concerns of both the AMA and the AAFP appear to be related to the possibility that pharmacists may wish to act as independent practitioners rather than as members of an interprofessional team coordinated by a physician. Research indicates that most physicians support an extended role for pharmacists as members of the health care team. Pharmacists and physicians (n = 197) working in 5 Tennessee nonacademic hospitals were surveyed regarding their perception of an increased role of pharmacists as part of the health care team.<sup>92</sup> A total of 83 responses were collected, for a response rate of 42.1%. Of the questionnaires returned, 60.8% were completed by physicians (n = 48). Nearly 92% of the physician respondents indicated that they believed that pharmacists contribute to the clinical care of patients, and 75% stated that they would be receptive to an expanded role for pharmacists in clinical settings. Most physician respondents also indicated that they frequently follow the recommendations made by pharmacists. Another study found that physicians perceived the contributions of clinical pharmacists to be both financially and clinically beneficial.<sup>115</sup>

The studies referenced above involved pharmacists working in primarily clinical roles as part of a health care team. These results may not be generalizable to physicians' perceptions of pharmacists who work independently from the physician. In a study in which 102 completed questionnaires were collected from physicians in West Virginia to obtain their opinions about partnership with a community pharmacist, approximately 60% of respondents supported the idea of collaborative practice agreements.<sup>116</sup> Physicians were least comfortable with community pharmacists making independent suggestions to patients about pharmacotherapy options and developing medication treatment plans in conjunction with the physician. These opinions contrast with the physicians' perceptions about pharmacists working in team-based settings.

The provision of CMM by psychiatric pharmacists working as part of the health care team fits into a pharmacist health care model that is consistent with the positions of both the AMA and the AAFP. Published studies indicate that CMM is also the process of care that is most likely to be viewed positively by physicians and nurses.<sup>117,118</sup> CMM is supported by CPNP and is currently practiced by many psychiatric pharmacists. It is likely that this practice model would be accepted by most physicians, nurses, and other health care providers because it recommends the use of a team approach in which the physician is still responsible for the patient's overall health care coordination and the pharmacist is a part of the health care team rather than an independent practitioner.

### **Payment for Services**

Currently, neither most pharmacists nor their employers receive payment for the provision of CMM or MTM services. One reason for this lack of payment is that pharmacists are not recognized as providers by the federal Social Security Act, although most states currently have some type of statute regarding the provider status of pharmacists. For this reason, federal and private payers do not routinely include pharmacists in their payment systems, a fact that makes it difficult to financially justify or support pharmacist positions in the provision of direct patient care.<sup>119</sup> Currently many institutions justify hiring psychiatric pharmacists on the basis of the value that they place on pharmacists' activities in improving patient outcomes, reducing risk, extending physician capacity, contributing to vital committees, and contributing to the educational mission of the facility. Some of the payment systems currently being used by pharmacists and pharmacy departments to support clinical pharmacy services and pharmacist salaries include grants, cost sharing with academic programs, or patient out-of-pocket payments, but these are generally not sustainable and reproducible. The following options more likely represent future payment systems for pharmacist services<sup>49,120,121</sup>:

- *Fee-for-service*. Pharmacists are paid per episode of service
- *Indirect payment*. Pharmacist services may be billed according to the "incident-to" physician billing mechanism, in which the physician is responsible for the direct supervision of the pharmacist.
- *Capitation*. Health systems are paid a set amount over a certain time period to provide covered services. These funds can be used for pharmacists' salaries or payment.
- *Cost avoidance*. Often used in hospital settings, this mechanism tracks medication-related interventions performed by pharmacists and estimates the cost savings that occur as a result of these pharmacy services.
- *Pay for performance*. Additional payments are provided when services meet quality metrics.

With the emphasis on quality of care and performancebased measures, future payment for psychiatric pharmacists will probably come from payments made to a health care team for quality of performance. Because future Medicare payments are likely to be tied to quality performance rather than to fees received for services,<sup>122</sup> it is crucial that psychiatric pharmacists pursue payment mechanisms that are consistent with those that will be espoused in the future. Payment as part of an integrated member of the team rather than fee-for-service is the most likely scenario, although the current fee-for-service payment structure is likely to continue until a transition can be made under payment reform.

The PCMH is an example of how a payment system for pharmacists who provide direct patient care as a member of the health care team would work. A portion of the standards established by the National Committee for Quality Assurance includes the use of nonphysicians to provide a range of services as part of the health care team.<sup>123</sup> This standard can be achieved by integrating psychiatric pharmacists, who are qualified to provide direct patient care, into the medical home model so that better service can be provided to those patients who have both chronic medical illnesses and psychiatric or neurologic disorders.<sup>49</sup> CMM, the process of care supported by CPNP, would be the service provided by the psychiatric pharmacist in the PCMH and would be similar to pharmacy care models in other health care systems.<sup>124</sup> However, if this standard of care is to become part of all PCMHs, it is necessary that Medicare Part B, private insurance companies, or employer groups recognize payment for CMM as a consistent pharmacy process of care that improves medication-related outcomes and decreases the overall cost of care.

As stated above, one of the biggest barriers to payment for pharmacists' services is the fact that pharmacists are not currently recognized as providers under the federal Social Security Act. It should be noted that some states, such as California, have already passed laws recognizing pharmacists as providers.<sup>125</sup> It is crucial to recognize that provider status alone will not translate into payment for the direct patient care services provided by a psychiatric pharmacist. Federal recognition would help ensure that direct patient care services provided by all pharmacists, acting as members of a health care team, could potentially be paid for, depending upon the scope of practice allowed by each state.

Nearly all states have provisions for physician-pharmacist collaborative practice agreements, although the scope of practice for a pharmacist varies depending on the state in which the pharmacist is licensed.<sup>126</sup> Additionally, each state may have different requirements regarding the clinical experience, training, education, or board certification that pharmacists must have if they are to provide certain types of direct patient care services.<sup>119</sup> What most states have in common is the recognition that pharmacists must have a certain level of training and experience before they can provide services to patients as teambased health care providers. This recognition is consistent with the proficiencies that ACCP has deemed necessary for qualified pharmacists. ACCP has further stated that qualified pharmacists engaged in direct patient care must be board certified through BPS (once board eligible) and must either have been granted clinical privileges through a credentialing system or have a collaborative drug therapy management agreement.<sup>127</sup> ACCP has defined direct patient care as follows:

Direct patient care practice involves the pharmacist's direct observation of the patient and his or her [ie, the pharmacist's] contributions to the selection, modification, and monitoring of patient-specific therapy. This is often accomplished within an interprofessional team or

through collaborative practice with another healthcare provider.  $^{^{\!\!\!\!\!^{128}}}$ 

Because of the nature of psychiatric pharmacy practice, direct patient care provided by a psychiatric pharmacist is exclusively conducted as part of a health care team, which includes the patient and his or her family.

## **Call to Action**

Pharmacists, pharmacy educators, physicians, other nonpharmacy health care providers, legislators, government officials, payers, patients, families, and advocacy groups must work together to overcome barriers that prevent patients with psychiatric or neurologic disorders from receiving team-based CMM. Below are the recommended action items (see Table) aimed at ensuring that all patients with psychiatric or neurologic disorders have access to a standardized consistent patient care process, such as CMM, provided by a psychiatric pharmacist working as a member of the health care team with the goal of improving medication-related outcomes and decreasing costs.

## **CPNP Position Statement**

- All patients with psychiatric and neurologic disorders should have access to comprehensive medication management provided by a psychiatric pharmacist.
- The demand for psychiatric services to treat psychiatric and neurologic disorders has dramatically increased. Psychiatric pharmacists can help meet this demand by working with a physician as part of a collaborative team to improve medication-related outcomes for patients with psychiatric or neurologic disorders.
- Psychiatric pharmacists have specialized training or substantial experience in working with patients with psychiatric or neurologic disorders. Board certification in Psychiatric Pharmacy from the Board of Pharmaceutical Specialties is the recommended method for recognizing that a pharmacist has the necessary knowledge and experience.
- Studies show that including a psychiatric pharmacist as a member of an interdisciplinary team is cost-effective and has a positive impact on clinical outcomes (eg, effectiveness, adherence) by optimizing pharmacotherapy while decreasing the incidence of adverse effects associated with medication. This impact, in turn, increases patients' engagement in treatment and improves their adherence to medication regimens.
- Comprehensive medication management (CMM) is a standard of care in which psychiatric pharmacists provide direct patient care by assessing *all* medications to determine that each medication is:

#### TABLE: Action Items

| Responsible<br>Party                                   | Action Steps   |
|--|--|
| Psychiatric<br>pharmacists                             | Make CMM the standard of practice for all patient care services  |
|  | Advocate for legislation that supports the<br>provision of direct patient care services,<br>specifically CMM, by qualified<br>pharmacists  |
|  | Collect outcome data that support the value<br>of psychiatric and neurologic pharmacy<br>services, specifically CMM services   |
|  | Ensure that all pharmacy students and<br>residents who complete advanced<br>practice pharmacy experiences or<br>rotations at sites serving patients with<br>psychiatric or neurologic disorders are<br>exposed to and trained in the provision<br>of CMM             |
| Pharmacy<br>educators                                  | Include a standardized patient care process,<br>such as CMM, as part of the standard<br>Doctor of Pharmacy curriculum  |
|  | Develop additional rotations that<br>emphasize the provision of patient care<br>through this model   |
|  | Include components within the didactic<br>and experiential curriculum that allow<br>for interaction with actual patients with<br>psychiatric or neurologic disorders and<br>that allow patients to talk about their<br>experiences with medications and<br>providers |
|  | Support the development of quality postgraduate training opportunities for aspiring psychiatric pharmacists  |
|  | Assure the presence of a board-certified<br>psychiatric pharmacist as a role model on<br>the faculty at every school of pharmacy   |
| Physicians,<br>health<br>care providers,               | Support CMM as the standard of practice<br>for patient care services provided by a<br>psychiatric pharmacist   |
| legislators,<br>government<br>officials, and<br>payers | Support legislation that advocates payment<br>for CMM provided by qualified<br>pharmacists   |
|  | Integrate psychiatric pharmacists as<br>members of the health care team at<br>practice sites and in medical homes  |
|  | Support payment for pharmacist-provided<br>direct patient care services under the<br>federal Social Security Act   |
| Patients, families,<br>and advocates                   | Demand access to patient care services provided by psychiatric pharmacists   |

- o Appropriate for the individual patient in terms of his or her diagnosis
- o Effective for the medical condition being treated
- o Safe, given patients' comorbid conditions and other medications taken and with regard to each medication's adverse effect profile
- o Able to be taken as intended and convenient for the patient.
- CMM is not a stand-alone service but is instead provided by the psychiatric pharmacist as part of the health care team, in collaboration with a physician. Studies have found that collaborative practice agreements between physicians and psychiatric pharmacists lead to positive outcomes and should be included as part of CMM. Evidence supports CMM as a process of care that reduces costs and improves medicationrelated outcomes. Additional studies are needed to assist in refining the process of care to further optimize clinical outcomes and cost-effectiveness.
- Mechanisms for paying for CMM services provided by psychiatric pharmacists must be identified if this service is to become a standard of care available to all patients with psychiatric or neurologic disorders.
- Psychiatric pharmacy is a recognized specialty, and psychiatric pharmacists make valuable contributions to patient care. We recommend that psychiatric pharmacists, pharmacy educators, physicians, other nonpharmacy health care providers, and legislators take action to ensure that all patients with psychiatric or neurologic disorders have access to CMM services provided by psychiatric pharmacists.

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| Study, y                              | Study Characteristics   |  |  |  |  |  |
|---------------------------------------|---|--|--|--|--|--|
| Outpatient                            |   |  |  |  |  |  |
| Adler et al, <sup>59</sup> 2004       | Study Design (Duration): Randomized controlled trial; control participants received usual care from PCP   |  |  |  |  |  |
|                                       | (6-mo intervention period with 18-mo follow-up)   |  |  |  |  |  |
|                                       | Setting: Nine primary care clinics  |  |  |  |  |  |
|                                       | Patient Population (Sample Size): MDD, dysthymia  |  |  |  |  |  |
|                                       | N = 533   |  |  |  |  |  |
|                                       | (intervention group, 268; control group, 265)   |  |  |  |  |  |
|                                       | Intervention: Pharmacists monitored medication therapy, provided therapeutic recommendations to PCPs, provided patient education and advice   |  |  |  |  |  |
|                                       | <b>Results:</b> Patients in the intervention group had higher adherence rates of antidepressant medication use at 6 mo than patients in the control group ( $57.5\%$ versus $46.2\%$ , $P = .03$ ).                         |  |  |  |  |  |
|                                       | Depression outcomes at 6 mo, based on mBDI scores, did not vary significantly between intervention and control groups but favored intervention group ( $P = .16$ ).   |  |  |  |  |  |
|                                       | <b>Comment:</b> Study did not exclude patients who were already taking antidepressants, who were<br>unwilling to try antidepressants, or who had comorbid psychiatric disorders.  |  |  |  |  |  |
|                                       | Pharmacists spent an average of 11 min per patient per month (average total: 70 min per patient).   |  |  |  |  |  |
|                                       | The most significant effect on medication adherence at 6 mo occurred in patients who were not taking antidepressants at enrollment (32.3% intervention versus 10.9% control; $P = .001$ ).                                  |  |  |  |  |  |
|                                       | Dose-response effect for time spent with pharmacist.  |  |  |  |  |  |
|                                       | Cost of pharmacists' time spent with patients and their PCP averaged between \$80 and \$100 per patient during 6 mo.  |  |  |  |  |  |
| Bond and Salinger, <sup>66</sup> 1979 | Study Design (Duration): Retrospective chart review   |  |  |  |  |  |
|                                       | (control group: historic "before" intervention)   |  |  |  |  |  |
|                                       | (up to 12 mo)   |  |  |  |  |  |
|                                       | Setting: Outpatient VA psychiatric clinic   |  |  |  |  |  |
|                                       | Patient Population (Sample Size): Schizophrenia   |  |  |  |  |  |
|                                       | N = 25  |  |  |  |  |  |
|                                       | (intervention group, 25; control group, 25)   |  |  |  |  |  |
|                                       | Intervention: Medication monitoring services  |  |  |  |  |  |
|                                       | Results: Decrease in hospital readmission.  |  |  |  |  |  |
|                                       | Decrease of $>$ 1300 d of hospitalization (P < .001).   |  |  |  |  |  |
|                                       | \$230 000 estimated savings in patient utilization.   |  |  |  |  |  |
|                                       | Decreases in number of reported adverse effects ( $P < .005$ ).   |  |  |  |  |  |
|                                       | 39% decrease in fluphenazine dosage.  |  |  |  |  |  |
|                                       | 42% decrease in anticholinergic use.  |  |  |  |  |  |
|                                       | Comment: Medication adjustment required psychiatrist approval.  |  |  |  |  |  |
|                                       | Possible selection bias because patients were selected for participation by psychiatrist.   |  |  |  |  |  |
| Caballero et al, <sup>71</sup> 2008   | Study Design (Duration): Naturalistic review  |  |  |  |  |  |
|                                       | (15 mo)   |  |  |  |  |  |
|                                       | Setting: Outpatient community health center in south Texas  |  |  |  |  |  |
|                                       | Patient Population (Sample Size): Various psychiatric illnesses; most common reasons for referral to clinic were depression, dementia/cognitive impairment, anxiety, and insomnia   |  |  |  |  |  |
|                                       | N = 96  |  |  |  |  |  |
|                                       | Intervention: Pharmacist consulted with PCP regarding therapy for psychiatric disorders; provided patient education and medication therapy management until therapy was optimized   |  |  |  |  |  |
|                                       | <b>Results:</b> More than 90% of pharmacists' clinical recommendations were accepted by physician or medical director.  |  |  |  |  |  |
|                                       | After 5.6 wk of active treatment, patients who were treated for depression or anxiety had a mean decrease in depression and anxiety symptoms as measured by HAM-D or HAM-A scores (decreases of 52% and 56%, respectively). |  |  |  |  |  |

| Study, y                          | Study Characteristics   |  |  |  |  |  |
|-----------------------------------|---|--|--|--|--|--|
|                                   | After 7.7 wk, patients who were treated for cognitive impairment/dementia had a mean decrease ir MMSE scores by 1.4 points, indicating a decrease in cognitive function.  |  |  |  |  |  |
|                                   | All patients who were treated for insomnia reported improvements in sleep.  |  |  |  |  |  |
|                                   | Estimated cost savings generated by the clinic during the 15-mo period: \$22 380.   |  |  |  |  |  |
|                                   | <b>Comment:</b> Many patients had comorbid psychiatric conditions.  |  |  |  |  |  |
|                                   | Pharmacist was available for limited hours.   |  |  |  |  |  |
| apoccia et al, <sup>61</sup> 2004 | Study Design (Duration): Randomized controlled trial  |  |  |  |  |  |
|                                   | (12 mo)   |  |  |  |  |  |
|                                   | Setting: Outpatient primary care clinic in Washington   |  |  |  |  |  |
|                                   | Patient Population (Sample Size): Depression  |  |  |  |  |  |
|                                   | N = 74  |  |  |  |  |  |
|                                   | (intervention group, 41; control group, 33)   |  |  |  |  |  |
|                                   | Intervention: Patients in intervention or "enhanced care" (EC) group were contacted by a  |  |  |  |  |  |
|                                   | pharmacist at predefined intervals; pharmacist collaborated with PCP to provide patient<br>education, dose adjustment for antidepressants, monitoring of patient adherence to therapy, and<br>management of adverse effects |  |  |  |  |  |
|                                   | <b>Results:</b> No significant difference between intervention and control groups in medication adherence at 12 mo ( $P = .91$ ).   |  |  |  |  |  |
|                                   | Mean SCL-20 and SF-12 scores improved significantly for both groups, indicating improvement in depression symptoms, but no significant difference between groups.   |  |  |  |  |  |
|                                   | No difference between groups in number of visits to any type of health care provider.   |  |  |  |  |  |
|                                   | No significant differences between groups for patient satisfaction with psychiatric or overall treatment.   |  |  |  |  |  |
|                                   | Comment: Most pharmacist interventions occurred by telephone.   |  |  |  |  |  |
|                                   | Both groups were encouraged to use all available resources in treatment of depression.  |  |  |  |  |  |
|                                   | Resources used by control group may not have been documented.   |  |  |  |  |  |
| rockett et al, <sup>69</sup> 2006 | Study Design (Duration): Nonrandomized controlled study   |  |  |  |  |  |
|                                   | (2 mo)  |  |  |  |  |  |
|                                   | Setting: 32 community pharmacies in rural Australia   |  |  |  |  |  |
|                                   | Patient Population (Sample Size): Depression  |  |  |  |  |  |
|                                   | N = 119   |  |  |  |  |  |
|                                   | (intervention group, 51; control group, 68)   |  |  |  |  |  |
|                                   | Intervention: Pharmacists received additional training via videoconference and provided additiona advice and support to patients when dispensing medications  |  |  |  |  |  |
|                                   | Results: No statistically significant difference in adherence between groups.   |  |  |  |  |  |
|                                   | Improvement in K10 score for both groups indicated improvement in depressive symptoms, but no significant difference between groups.  |  |  |  |  |  |
|                                   | No significant difference between groups in improvement on Drug Attitude Index.   |  |  |  |  |  |
|                                   | <b>Comment:</b> Some patients were just starting to take antidepressants, whereas others had been taking them for some time when beginning this study.  |  |  |  |  |  |
|                                   | Not a randomized study.   |  |  |  |  |  |
|                                   | Very short duration of study.   |  |  |  |  |  |
|                                   | Some control group pharmacists were later found to have provided services similar to those provided by the intervention group.  |  |  |  |  |  |
| inley et al, <sup>68</sup> 2002   | Study Design (Duration): Prospective controlled cohort  |  |  |  |  |  |
|                                   | (6 mo)  |  |  |  |  |  |
|                                   | Setting: Primary care clinic within HMO   |  |  |  |  |  |
|                                   | Patient Population (Sample Size): Depression  |  |  |  |  |  |
|                                   | N = 220   |  |  |  |  |  |
|                                   | (intervention group, 91; control group, 129)  |  |  |  |  |  |

| Study, y                        | Study Characteristics  |  |  |  |  |  |
|---------------------------------|--|--|--|--|--|--|
|                                 | Intervention: Pharmacists provided patient education, assessed medication therapy, and provided therapeutic recommendations; pharmacists had limited prescribing privileges under protocol   |  |  |  |  |  |
|                                 | <b>Results:</b> Significant increase in medication adherence among patients in intervention group (medication possession ratio of $0.81$ in intervention group versus $0.66$ in control group; $P < .005$ ).   |  |  |  |  |  |
|                                 | Significant increase in number of patients who completed 6 mo of antidepressant therapy in the intervention group (76% versus 53% control group; $P = .008$ ).   |  |  |  |  |  |
|                                 | Higher patient satisfaction levels in intervention group ( $P < .05$ ).  |  |  |  |  |  |
|                                 | Larger decrease in PCP visits in intervention group (39.4% decrease for intervention group versus 12.2% decrease for control; $P = .007$ ).  |  |  |  |  |  |
|                                 | Comment: Not a randomized study.   |  |  |  |  |  |
|                                 | Intervention involved both telephone calls and face-to-face visits with the pharmacist.  |  |  |  |  |  |
| inley et al, <sup>60</sup> 2003 | Study Design (Duration): Randomized controlled trial   |  |  |  |  |  |
|                                 | (6 mo)   |  |  |  |  |  |
|                                 | Setting: Primary care center within HMO in northern California   |  |  |  |  |  |
|                                 | Patient Population (Sample Size): Depression   |  |  |  |  |  |
|                                 | N = 125  |  |  |  |  |  |
|                                 | (intervention group, 75; control group, 50)  |  |  |  |  |  |
|                                 | <b>Intervention:</b> Pharmacist followed up with patients frequently to assess therapeutic effect, adverse effects, and adherence; pharmacist could titrate antidepressant dose as indicated by HMO guidelines and had limited prescribing privileges for ancillary medications under protocol |  |  |  |  |  |
|                                 | <b>Results:</b> Patients in the intervention group were more likely to complete the continuation phase of treatment ( $67\%$ versus $48\%$ control; $P = .038$ ).  |  |  |  |  |  |
|                                 | Patients in intervention group had 15% decrease in visits to PCP compared with 2% decrease in control group, but difference was not statistically significant ( $P = .14$ ).   |  |  |  |  |  |
|                                 | 76% in the intervention group were compliant with the early phase of treatment versus 60% in t control group (OR, 2.11; 95% Cl, 0.97-4.58; $P = .057$ ).   |  |  |  |  |  |
|                                 | Medication costs were higher for patients in the intervention group than for patients in the control group, but difference was not statistically significant.  |  |  |  |  |  |
|                                 | No statistically significant difference in clinical response as determined by BIDS and WSDS scores.  |  |  |  |  |  |
|                                 | Patient satisfaction was higher for intervention group (P $<$ .05 for all survey measures).  |  |  |  |  |  |
|                                 | <b>Comment:</b> Pharmacist spent an average of 71 minutes with each patient.   |  |  |  |  |  |
|                                 | Cost-effectiveness was not analyzed.   |  |  |  |  |  |
|                                 | Pharmacist met with patients both face-to-face and by telephone.   |  |  |  |  |  |
|                                 | More patients in intervention group changed antidepressants during study (19% versus 4% control; $P = .016$ ).   |  |  |  |  |  |
|                                 | High provider satisfaction with pharmacist interventions.  |  |  |  |  |  |
| inley et al, <sup>73</sup> 2011 | Study Design (Duration): Prospective nonrandomized cohort  |  |  |  |  |  |
|                                 | (18 mo)  |  |  |  |  |  |
|                                 | Setting: Two outpatient clinics in Asheville, North Carolina   |  |  |  |  |  |
|                                 | Patient Population (Sample Size): Depression   |  |  |  |  |  |
|                                 | N = 130  |  |  |  |  |  |
|                                 | Intervention: Pharmacists met face-to-face with patients for evaluation and management of<br>medication therapy and patient education  |  |  |  |  |  |
|                                 | <b>Results:</b> Patients had clinically significant improvement in PHQ-9 score, indicating improvement in depressive symptoms ( $P < .0001$ ).   |  |  |  |  |  |
|                                 | Estimated total savings for employer of \$41 881 per year for the 48 enrollees who were evaluated for cost savings.  |  |  |  |  |  |
|                                 | Comment: No control group.   |  |  |  |  |  |
| <i>.</i>                        | Clinical improvements were greatest for those patients with severe depression at baseline, compare with those with mild or moderate depression.  |  |  |  |  |  |
| Gray et al, <sup>64</sup> 1979  | Study Design (Duration): Retrospective chart review;   |  |  |  |  |  |
|                                 | (control group: historic "before" control)   |  |  |  |  |  |

| Study, y                           | Study Characteristics  |
|------------------------------------|--|
|                                    | (3 mo)   |
|                                    | Setting: Outpatient VA psychiatric clinic  |
|                                    | Patient Population (Sample Size): Psychiatric disorders undisclosed  |
|                                    | N = 19   |
|                                    | Intervention: Medication monitoring and weekly medication groups; adjust or prescribe medication<br>under protocol   |
|                                    | Results: Nonsignificant improvement in clinical outcomes.  |
|                                    | Significant decrease in adverse effects ( $P < .005$ ).  |
|                                    | Significant decrease in number of prescribed medications ( $P < .05$ ).  |
|                                    | Improvement in patients' drug knowledge.   |
|                                    | Comment: Patients selected had stable and chronic clinical status.   |
| lartlaub et al, <sup>67</sup> 1993 | Study Design (Duration): Prospective cohort study not randomized by clinics  |
|                                    | (6 mo before versus 6 mo after intervention)   |
|                                    | Setting: Eleven clinics in a medical group practice (HMO model)  |
|                                    | Patient Population (Sample Size): Physicians prescribing benzodiazepines to elderly  |
|                                    | Group 1: 2 clinics with 9049 patients  |
|                                    | Group 2: 8 clinics with 6279 patients  |
|                                    | Control: 1 clinic with 8012 patients   |
|                                    | Intervention: Education program to physicians: group 1 received presentations, written materials, brief individual review, and feedback; group 2 received presentation and written materials   |
|                                    | Results: No impact on benzodiazepine prescribing practices for either group.   |
|                                    | Comment: Complex evaluation of the effect of one-to-one interactions on prescribing practices.   |
| obeck et al, <sup>65</sup> 1989    | Study Design (Duration): Retrospective chart review and satisfaction questionnaire   |
|                                    | (control group: historic "before" control)   |
|                                    | (9 mo: 6 mo before intervention $+$ 3 mo after intervention)   |
|                                    | Setting: Outpatient psychiatric VA clinic  |
|                                    | Patient Population (Sample Size): Various psychiatric disorders  |
|                                    | N = not applicable   |
|                                    | (4734 visits before intervention versus 2662 visits after).  |
|                                    | Intervention: Chart review, treatment recommendations, medication education (clinician and patient), kinetic dosing services, adverse effect monitoring, medication use evaluations  |
|                                    | Results: 66% of recommendations accepted; very favorable provider survey response.   |
|                                    | Cost savings of \$22 241.  |
|                                    | Comment: Savings because fewer and less-expensive medications were used.   |
|                                    | Measure of clinical outcomes unknown.  |
| Rickles et al, <sup>62</sup> 2005  | Study Design (Duration): Randomized controlled trial   |
|                                    | (3-mo intervention period with 5-mo follow-up)   |
|                                    | Setting: Eight community pharmacies in Wisconsin   |
|                                    | Patient Population (Sample Size): Depression   |
|                                    | N = 60   |
|                                    | (intervention group, 28; control group, 32)  |
|                                    | Intervention: Pharmacists called patients in intervention group once monthly for 3 mo to provide pharmacist-guided education and monitoring  |
|                                    | <b>Results:</b> The intervention group was significantly more likely to provide feedback to the pharmacist regarding their medication therapy (frequency of patient feedback to pharmacist score of 23 for intervention group versus 11 for control group; $P < .001$ ). |
|                                    | The rate of missed doses was significantly lower for the intervention group than for the control group, but this finding was not statistically significant in an ITT analysis that included patients who did not complete the study.                                     |

| Study, y                             | Study Characteristics  |
|--------------------------------------|--|
|                                      | The intervention had a statistically significant ( $P < .05$ ) impact on antidepressant knowledge, beliefs about antidepressants, and awareness of treatment progress.   |
|                                      | No significant difference in improvement of depression symptoms between the intervention and control groups as determined by BDI-II scores; however, both groups showed statistically significant improvement in symptoms ( $P \leq .001$ ).   |
|                                      | <b>Comment:</b> Intervention group patients were more likely to have history of psychiatric medication use even though the study was randomized.   |
| Rosen and Holmes, <sup>70</sup> 1978 | Study Design (Duration): Retrospective chart review (control group: nonpharmacist group)   |
|                                      | (36 mo)  |
|                                      | Setting: Eight community mental health clinics   |
|                                      | Patient Population (Sample Size): Outpatients with chronic psychiatric illnesses   |
|                                      | N = 178  |
|                                      | (intervention group, 30; control group, 148)   |
|                                      | Intervention: Case-management services (eg, drug monitoring, education, dose adjustment based on protocol)   |
|                                      | Results: Intervention group reported greater improvement in overall health.  |
|                                      | Trend toward greater patient satisfaction, statistically significant difference only in personal adjustment  |
|                                      | Cost 2.5 times higher in psychiatrist group than in pharmacist group.  |
|                                      | Comment: Validated measure of clinical outcomes lacking.   |
| /alenstein et al, <sup>63</sup> 2011 | Study Design (Duration): Randomized controlled trial   |
|                                      | (12 mo)  |
|                                      | Setting: Four outpatient VA clinics  |
|                                      | Patient Population (Sample Size): Schizophrenia, schizoaffective disorder, bipolar disorder  |
|                                      | N = 118  |
|                                      | (intervention group, 58; control group, 60)  |
|                                      | Intervention: Patients in Meds-Help intervention group received unit-of-use packaging for all medications, an educational session, and refill reminders 2 wk before refills were due; clinicians were notified if refills were not picked up on time; educational medication session was conducted by pharmacist |
|                                      | <b>Results:</b> Statistically significant improvement in MPR for the intervention group from baseline to 12 mo, indicating that the intervention group had improved adherence to medication therapy (0.54 to 0.86 versus 0.55 to 0.62 for control group; $P < .0001$ ).  |
|                                      | No statistically significant differences between groups in improvement of symptoms, as determined by PANSS scores.   |
|                                      | No statistically significant differences between groups in QWB scores.   |
|                                      | No statistically significant difference between groups in patient satisfaction, as determined by CSQ-8 scores.   |
|                                      | <b>Comment:</b> Many interventions were completed by pharmacy technicians under pharmacist supervision.  |
| Wang et al, <sup>72</sup> 2011       | Study Design (Duration): Uncontrolled study  |
|                                      | (7 mo)   |
|                                      | Setting: Outpatient "safety-net" clinic in Skid Row (Los Angeles)  |
|                                      | Patient Population (Sample Size): Various psychiatric illnesses  |
|                                      | N = 36   |
|                                      | Intervention: Pharmacist met with patients for patient education, monitoring of therapeutic effect<br>and adverse effects, and administration of rating scales; treatment plan was collaborative effort<br>between pharmacist and PCP  |
|                                      | <b>Results:</b> Almost 77% of patients showed clinical improvement: mean change in PHQ-9 score from baseline to 7 mo was 5.7 $\pm$ 5.7 ( <i>P</i> = .02).  |
|                                      | Comment: No control group.   |
|                                      | No economic outcome data.  |
|                                      | Pharmacist was reportedly well received by the treatment team.   |

| Study, y                              | Study Characteristics   |  |  |  |  |
|---------------------------------------|---|--|--|--|--|
| Inpatient                             |   |  |  |  |  |
| Alexander et al, <sup>90</sup> 1983   | Study Design (Duration): Retrospective chart review   |  |  |  |  |
|                                       | (control group: historic "before" control)  |  |  |  |  |
|                                       | Setting: Inpatient psychiatric VA hospital  |  |  |  |  |
|                                       | (compared 1-mo evaluation period)   |  |  |  |  |
|                                       | Patient Population (Sample Size): Inpatients with various psychiatric disorders   |  |  |  |  |
|                                       | (58 patients before intervention versus 49 patients after intervention)   |  |  |  |  |
|                                       | Intervention: Education program for psychiatric staff (1 h/wk for 2 y)  |  |  |  |  |
|                                       | Results: Significant decrease in the number of multiple daily doses of psychiatric medications.   |  |  |  |  |
|                                       | Comment: Disease severity between groups unknown.   |  |  |  |  |
|                                       | No economic analysis.   |  |  |  |  |
| Berchou, <sup>82</sup> 1982           | Study Design (Duration): Retrospective chart review   |  |  |  |  |
|                                       | (control group: historic "before")  |  |  |  |  |
|                                       | Also compared intervention site vs. same factors at another similar facility with no intervention   |  |  |  |  |
|                                       | (12 mo)   |  |  |  |  |
|                                       | Setting: Institution for mental retardation   |  |  |  |  |
|                                       | Patient Population (Sample Size): Inpatients with behavioral disorders  |  |  |  |  |
|                                       | 715 at intervention site; 1049 at control site  |  |  |  |  |
|                                       | Intervention: Treatment recommendation and educational session provided to multidisciplinary tean   |  |  |  |  |
|                                       | <b>Results:</b> Long-term medication use decreased by 19% ( $P < .001$ ).   |  |  |  |  |
|                                       | Antipsychotics more commonly used at control site.  |  |  |  |  |
|                                       | Comment: Control site did not have a multidisciplinary team.  |  |  |  |  |
|                                       | Antipsychotic use measured only at end point at control site.   |  |  |  |  |
|                                       | Difficult to measure pharmacist's impact.   |  |  |  |  |
| Canales et al, <sup>85</sup> 2001     | Study Design (Duration): Prospective cohort; control group: historic "before" control   |  |  |  |  |
|                                       | (13 mo: 6 mo before intervention to 7 mo after intervention)  |  |  |  |  |
|                                       | Setting: Psychiatric inpatient VA hospital  |  |  |  |  |
|                                       | Patient Population (Sample Size): Patients with various psychiatric illnesses   |  |  |  |  |
|                                       | N = 93  |  |  |  |  |
|                                       | (45 in intervention group; 48 in control group)   |  |  |  |  |
|                                       | Intervention: Clinical services provided (obtaining drug histories, baseline assessments, drug monitoring, treatment recommendations, drug education)   |  |  |  |  |
|                                       | <b>Results:</b> Better clinical outcomes for intervention group with thought disorders: 93% with $>$ 20% decrease in scores on the BPRS versus 23% decrease for control participants ( $P < .05$ ). |  |  |  |  |
|                                       | 13% of intervention patients with CGI score $\geq$ 4 versus 63% of control participants (P $<$ .05).  |  |  |  |  |
|                                       | Better clinical outcomes for mood disorders: 65% of intervention group with $\geq$ 50% decline on HAM-D versus 9% of control participants ( $P < .003$ ).   |  |  |  |  |
|                                       | Greater improvements in adverse-effect scales with intervention group.  |  |  |  |  |
|                                       | No difference in length of stay between groups.   |  |  |  |  |
|                                       | Daily drug cost of \$252 per patient in intervention group versus \$151 in control group ( $P = NS$ ).  |  |  |  |  |
|                                       | Cost-effectiveness analysis reported cost of successful outcome as $2.48$ per patient (eg, $> 20\%$ decrease in scores on BPRS.   |  |  |  |  |
|                                       | <b>Comment:</b> Superior improvements may be due to increased use of atypical antipsychotics (mostly risperidone).  |  |  |  |  |
|                                       | Lacked analysis of total resource utilization, functional outcomes, and patient satisfaction.   |  |  |  |  |
| Ellenor and Frisk, <sup>81</sup> 1977 | Study Design (Duration): Retrospective chart review; control group: historic "before" control   |  |  |  |  |
|                                       | (24 mo)   |  |  |  |  |
|                                       | Setting: Institution for mental retardation   |  |  |  |  |
|                                       | Patient Population (Sample Size): Inpatients with behavioral complications  |  |  |  |  |

| Study, y                         | Study Characteristics   |  |  |  |  |  |
|----------------------------------|---|--|--|--|--|--|
|                                  | N = 208   |  |  |  |  |  |
|                                  | Intervention: Evaluated drug therapy and outcomes   |  |  |  |  |  |
|                                  | <b>Results:</b> Medication use (eg, antipsychotics, antidepressants) decreased by 37% ( $P$ < .001).  |  |  |  |  |  |
|                                  | Annual savings of $>$ \$10 000.   |  |  |  |  |  |
|                                  | No relapse in behavior reported.  |  |  |  |  |  |
|                                  | Increase in maladaptive behavior not statistically significant.   |  |  |  |  |  |
|                                  | <b>Comment:</b> Results suggest overuse of medications for controlling behavioral complications in the mentally disabled.   |  |  |  |  |  |
| noue, <sup>83</sup> 1982         | Study Design (Duration): Retrospective chart review; control group: historic "before" control   |  |  |  |  |  |
|                                  | (60 mo)   |  |  |  |  |  |
|                                  | Setting: Facility for patients with mental disabilities   |  |  |  |  |  |
|                                  | Patient Population (Sample Size): Inpatients with behavioral disturbances   |  |  |  |  |  |
|                                  | N = 680   |  |  |  |  |  |
|                                  | Intervention: Medication management review (eg, medication recommendations/monitoring)  |  |  |  |  |  |
|                                  | <b>Results:</b> 73% of recommendations immediately accepted.  |  |  |  |  |  |
|                                  | 45% decrease in number of psychotropic drugs prescribed.  |  |  |  |  |  |
|                                  | 50% of patients had improvements in cognition.  |  |  |  |  |  |
|                                  | 8% had symptom worsening.   |  |  |  |  |  |
|                                  | Comment: Used validated instruments to monitor efficacy.  |  |  |  |  |  |
|                                  | Pharmacist time commitment and economic analysis not provided.  |  |  |  |  |  |
| Marino et al, <sup>89</sup> 2010 |   |  |  |  |  |  |
| Vianno et al, - 2010             | Study Design (Duration): Retrospective chart review<br>(18 mo)  |  |  |  |  |  |
|                                  | Setting: Psychiatric hospital in Florida  |  |  |  |  |  |
|                                  | Patient Population (Sample Size): Various psychiatric disorders   |  |  |  |  |  |
|                                  | N = 2220 interventions  |  |  |  |  |  |
|                                  | Intervention: Pharmacists provided clarification of orders, formulary conversion, dose recommendations and adjustments, therapeutic recommendations, and laboratory monitoring  |  |  |  |  |  |
|                                  | Results: Estimated cost savings of \$125 500 for the 18-mo time frame.  |  |  |  |  |  |
|                                  | Overall rate of acceptance of interventions, 98.8%.   |  |  |  |  |  |
|                                  | Acceptance rates were 97.7% for faculty clinical pharmacists, 99.8% for hospital staff pharmacists, and 87.5% for student pharmacists.  |  |  |  |  |  |
|                                  | Comment: Documentation of interventions was voluntary.  |  |  |  |  |  |
|                                  | Most interventions were made by hospital staff pharmacists.   |  |  |  |  |  |
| ИсКее, <sup>84</sup> 1994        | Study Design (Duration): Retrospective chart review of clinical pharmacy services   |  |  |  |  |  |
|                                  | (compared results of 12 mo of preclinical pharmacy services with results of 12 mo of clinical pharmacy services)  |  |  |  |  |  |
|                                  | Setting: Intermediate care facility for the developmentally disabled  |  |  |  |  |  |
|                                  | Patient Population (Sample Size): Developmentally disabled  |  |  |  |  |  |
|                                  | N = 446   |  |  |  |  |  |
|                                  | (71% had profound mental disability [IQ lower than 20–25]; 50% had comorbid seizure disorder)   |  |  |  |  |  |
|                                  | Intervention: Focused medication regimen review by clinical pharmacy services (eg, evaluation of drug regimen, clear indication for medication use, appropriate dose and schedule, need to contact prescriber to discuss drug regimen issues) |  |  |  |  |  |
|                                  | <b>Results:</b> Decreases in pharmacy cost per patient per day (\$2.98 versus \$2.38) and in medication doses per patient (16.1 versus 9.8).  |  |  |  |  |  |
|                                  | Savings in nursing administrative time per month was 1057 h.  |  |  |  |  |  |
|                                  | Decrease of more than 18% in pharmacy expenditures.   |  |  |  |  |  |
|                                  | <b>Comment:</b> Response of physicians and nurses to pharmacy clinical services was positive.   |  |  |  |  |  |
| ИсКее, <sup>129</sup> 1996       | Study Design (Duration): Retrospective qualitative analysis   |  |  |  |  |  |
|                                  | Setting: Intermediate care facility for the developmentally disabled (ICF-DD)   |  |  |  |  |  |

| Study, y                        | Study Characteristics   |  |  |  |  |
|---------------------------------|---|--|--|--|--|
|                                 | (compared 5 y of pharmacist-coordinated treatment-team services)  |  |  |  |  |
|                                 | Patient Population (Sample Size): Developmentally disabled  |  |  |  |  |
|                                 | N = 365   |  |  |  |  |
|                                 | Intervention: Pharmacists scheduled quarterly meetings of treatment team to implement a drug review model   |  |  |  |  |
|                                 | Results: Decrease in medication doses per resident (16 to 9–10 doses per day).  |  |  |  |  |
|                                 | Decrease in the use of antipsychotics.  |  |  |  |  |
|                                 | Shift to more frequent monotherapy and duotherapy of AED regimens for effective seizure control.  |  |  |  |  |
|                                 | Pharmacy cost per resident-day increased (probably because the facility used newer, safer, more-<br>expensive AEDs and antipsychotics).   |  |  |  |  |
|                                 | Comment: Pharmacists discontinued unnecessary medications.  |  |  |  |  |
|                                 | Results demonstrated that clinical pharmacy services met both the residents' needs and the Health<br>Care Financing Administration–mandated drug regimen review standard for this ICF-DD.   |  |  |  |  |
| cKee et al, <sup>130</sup> 1999 | Study Design (Duration): 3-mo screening and 3-mo prospective chart review   |  |  |  |  |
|                                 | (before and after assessments were compared for each resident regarding documented adverse medication experiences)  |  |  |  |  |
|                                 | Setting: Intermediate care facility for the developmentally disabled  |  |  |  |  |
|                                 | Patient Population (Sample Size): Mentally retarded   |  |  |  |  |
|                                 | N = 417   |  |  |  |  |
|                                 | Intervention: Pharmacist-led multidisciplinary program to identify appropriately documented information on adverse medication experiences   |  |  |  |  |
|                                 | Results: Allergy information was updated for 30% of residents with no previous documentation.   |  |  |  |  |
|                                 | <b>Comment:</b> Study emphasizes the important role of pharmacists in a medication event clarification process aimed at promoting safe, effective, rational drug therapy for several medication categories (ie, antipsychotics, antibiotics, analgesics, intravenous imaging dyes). |  |  |  |  |
| aklad et al, <sup>88</sup> 1984 | Study Design (Duration): Retrospective chart review   |  |  |  |  |
|                                 | (control group: historic "before" control)  |  |  |  |  |
|                                 | (compared results of two 3-mo evaluation periods)   |  |  |  |  |
|                                 | Setting: Inpatient psychiatric facility in academic medical center  |  |  |  |  |
|                                 | Patient Population (Sample Size): Acute schizophrenia   |  |  |  |  |
|                                 | N = 61  |  |  |  |  |
|                                 | (30 after intervention versus 31 control participants)  |  |  |  |  |
|                                 | Intervention: Medication monitoring, consultation, patient education  |  |  |  |  |
|                                 | <b>Results:</b> Statistically significant decreases in the number of antipsychotics and anticholinergics use $(P < .005)$ .   |  |  |  |  |
|                                 | Nonsignificant increase in antipsychotic dosage.  |  |  |  |  |
|                                 | Larger increase in discharge rates and lower readmission rates for intervention group.  |  |  |  |  |
|                                 | <b>Comment:</b> Transfer of patients to other units was a confounding factor.   |  |  |  |  |
|                                 | Unknown which intervention was most influential.  |  |  |  |  |
| 80                              | No cost analysis.   |  |  |  |  |
| hmidt et al, <sup>80</sup> 1998 | Study Design (Duration): Randomized control study (15 intervention versus 18 control)   |  |  |  |  |
|                                 | (12 mo)   |  |  |  |  |
|                                 | Setting: Thirty-three nursing homes in Sweden   |  |  |  |  |
|                                 | Patient Population (Sample Size): Elderly patients with various psychiatric illnesses   |  |  |  |  |
|                                 | N = 1805  |  |  |  |  |
|                                 | (562 patients at intervention sites versus 1243 patients at control sites)  |  |  |  |  |
|                                 | Intervention: Monthly multidisciplinary team meetings (ie, pharmacist, physicians, nurses, nurse aides) to review psychotropic drug therapy   |  |  |  |  |
|                                 | <b>Results:</b> Statistically significant decrease in use of antipsychotics in intervention group (19% versus 7%; $P = .007$ ).   |  |  |  |  |

| <b>APPENDIX TABLE:</b> | Impact of | pharmacists in | psychiatri | c settings: su | mmary of | studies. | (continued) |
|------------------------|-----------|----------------|------------|----------------|----------|----------|-------------|
|                        |           |                |            |                |          |          |             |

| Study, y                          | Study Characteristics  |  |  |  |  |
|-----------------------------------|--|--|--|--|--|
|                                   | Statistically significant increase in acceptable prescribing of anxiolytics for intervention group (21% versus 14%; $P = .002$ ).  |  |  |  |  |
|                                   | Comment: Number of intervention sites smaller than number of control sites.  |  |  |  |  |
|                                   | No clinical outcome measures, and no cost analysis performed.  |  |  |  |  |
| Stimmel et al, <sup>86</sup> 1982 | <b>Study Design (Duration):</b> Retrospective cohort; 3 pharmacists versus two psychiatrists prescribing (unblinded).  |  |  |  |  |
|                                   | Quality of prescribing practices graded by expert panel  |  |  |  |  |
|                                   | (not applicable)   |  |  |  |  |
|                                   | Setting: Inpatient psychiatric facility  |  |  |  |  |
|                                   | Patient Population (Sample Size): Hospitalized patients with various psychiatric disorders   |  |  |  |  |
|                                   | N = 158 prescriptions for intervention group; 120 prescriptions for control group  |  |  |  |  |
|                                   | Intervention: Prescribe under protocol by physician supervision  |  |  |  |  |
|                                   | <b>Results:</b> Pharmacist prescribing was significantly better than psychiatrist prescribing for antipsychotics and antidepressants.  |  |  |  |  |
|                                   | Anticholinergic prescribing was similar between groups.  |  |  |  |  |
|                                   | <b>Comment:</b> Quality guidelines developed by American Psychological Association task force.   |  |  |  |  |
|                                   | No economic analysis.  |  |  |  |  |
| Suehs et al, <sup>79</sup> 2011   | Study Design (Duration): Retrospective chart review  |  |  |  |  |
|                                   | (g mo)   |  |  |  |  |
|                                   | Setting: State psychiatric hospital in Texas   |  |  |  |  |
|                                   | Patient Population (Sample Size): Various psychiatric disorders  |  |  |  |  |
|                                   | N = 105  |  |  |  |  |
|                                   | Intervention: Pharmacists made recommendations, including initiating new medication therapy a discontinuing current medications, or obtaining laboratory results                             |  |  |  |  |
|                                   | <b>Results:</b> 66.9% of pharmacist recommendations were accepted.   |  |  |  |  |
|                                   | Statistically significant correlation between improvements in CGI-S scores and higher rates of implementation of pharmacist recommendations ( $P = .036$ ), indicating improvement of sympto |  |  |  |  |
|                                   | Correlation between implementation of pharmacist recommendation and improved CGI-I scores was not statistically significant.   |  |  |  |  |
|                                   | Comment: No economic outcomes.   |  |  |  |  |
|                                   | Patients were most commonly referred for consultation because of aggression or lack of response to treatment.  |  |  |  |  |

 $\begin{array}{l} \mathsf{AED} = \mathsf{antiepileptic} \ drug; \ \mathsf{BDI-II} = \mathsf{Beck} \ \mathsf{Depression} \ \mathsf{Inventory-II}; \ \mathsf{BIDS} = \mathsf{Brief} \ \mathsf{Intellectual} \ \mathsf{Disability} \ \mathsf{Scale}; \ \mathsf{BPRS} = \mathsf{Brief} \ \mathsf{Psychiatric} \ \mathsf{Rating} \ \mathsf{Scale}; \ \mathsf{CGI} = \mathsf{Clinical} \ \mathsf{Global} \ \mathsf{Impression}; \ \mathsf{CGI-I} = \mathsf{Clinical} \ \mathsf{Global} \ \mathsf{Impression}; \ \mathsf{FMO} = \mathsf{Hailth} \ \mathsf{Mathon} \ \mathsf{Rating} \ \mathsf{Scale}; \ \mathsf{CGI-I} = \mathsf{Impression} \ \mathsf{Impression}; \ \mathsf{HMO} = \mathsf{Health} \ \mathsf{Maintenance} \ \mathsf{Organization}; \ \mathsf{ICF-DD} = \mathsf{Intermediate} \ \mathsf{care} \ \mathsf{facility}; \ \mathsf{for} \ \mathsf{the} \ \mathsf{developmentally} \ \mathsf{develop}; \ \mathsf{MSE} = \mathsf{Mini-Mental} \ \mathsf{State} \ \mathsf{Examination}; \ \mathsf{MPR} = \mathsf{Impression} \ \mathsf{Intermediate} \ \mathsf{Care} \ \mathsf{State} \$