

Executive Summary

Survey of U.S. Psychiatrists Reveals Support for Delegating Authority to Pharmacists to Administer Long-Acting Injectable Antipsychotic Therapies to Patients Living With Serious Mental Illness

Conducted and Reported by KRC Research
Commissioned by Janssen Pharmaceuticals, Inc.

Background

An estimated 9.8 million adults in the United States lives with a serious mental illness (SMI),^{1,2} such as schizophrenia, which affects approximately 2.2 million adults in the United States.^{3,4} Individuals with SMI, including those with schizophrenia, may be treated with physician-prescribed injections of long-acting antipsychotic injectable therapies (LAIs). However, individuals whose only route to LAI administration is through a psychiatrist's or other physician's office may have challenges accessing medication, which may lead to nonadherence.

Only about 25,000 psychiatrists are practicing nationwide, and there is a growing shortage of primary care providers.^{5,6} In contrast, more than 181,000 retail pharmacists are employed in the United States,⁷ and the numbers are increasing.⁸ Pharmacists can play an important role supporting physicians in providing care to individuals with SMI.

Many states allow retail and community pharmacies to serve as alternate injection centers for patients in order to carry out a physician-directed treatment plan.⁹ Additional states may improve healthcare delivery for individuals with SMI by giving physicians the option to delegate administration of physician-prescribed LAIs to pharmacists.

Study Overview and Design

Janssen Pharmaceuticals, Inc., funded a survey to understand psychiatrists' opinions about the option to delegate their authority to administer LAIs to appropriately trained pharmacists for patients living with SMI. KRC Research, www.krcresearch.com/, a full-service public opinion company, was retained to conduct this research study. Janssen had input into the scope of work as well as the questionnaire, but not into the collection, processing or analysis of the data, or the final report.

The nationally representative telephone survey of 200 psychiatrists was conducted between April 5, 2016, and June 10, 2016. The margin of error is +/-6.9 percentage points at the 95% confidence level. The average interview length was about 22 minutes.

Objectives

The primary objective of the study was to understand psychiatrists' opinions about the option to delegate their authority to administer LAIs to appropriately trained pharmacists for patients living with SMI. The research also examined:

- Psychiatrists' perceptions of challenges related to access and adherence to medication in SMI patients;
- Challenges and barriers associated with administering LAIs, including capacity to store and dispose of LAIs, as well as psychiatrist or nurse availability to administer the injections;
- Attitudes toward sites of care for administering LAIs;
- Level of support for giving psychiatrists/physicians the option to delegate;
- Preference to administer LAIs vs. have LAIs administered by other trained medical professionals;
- Reasons for support or causes for concern regarding LAI delegation; and
- Factors that would enable psychiatrist support of delegation (among those initially hesitant).

Key Findings Summary

Main takeaways from the study are as follows:

- Nine in 10 psychiatrists report that medication nonadherence among patients living with SMI is a major problem.
- On average, over the past five years, psychiatrists in our survey report treating about 1 in 5 (22%) patients living with SMI with LAIs.
- The large majority of psychiatrists (71%) prefer to delegate administration of LAI injections to another medical professional, mainly because it gives them more time for consulting with patients to meet their psychological needs.
- Half of psychiatrists (52%) are not sure whether their state allows them to delegate authority to appropriately trained pharmacists to administer injections.
- The large majority of psychiatrists (68%) support having the option to delegate to appropriately trained pharmacists.
 - Key benefits they note: Delegation will make treatment more accessible and convenient to patients, and pharmacies have the capacity to stock and store LAIs.
 - Key concerns they note: Pharmacists may not have access to patient records, may not be equipped to handle adverse reactions to LAIs, and may not report back to psychiatrists.

Detailed Findings

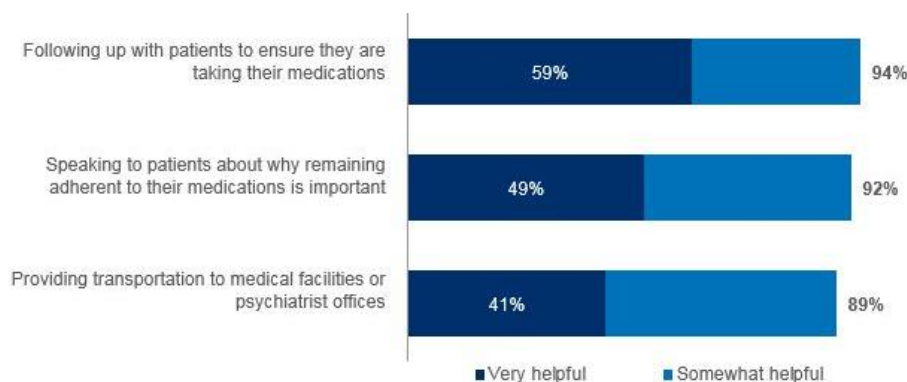
Treatment Adherence: Challenges and Ways to Address Them

The survey was carefully designed in a manner in which each section builds upon the section of the survey that precedes it—and thus started off broadly on the topic of adherence, generally.

According to an overwhelming 91% of psychiatrists, medication nonadherence, in general, is a major problem as it relates to patients living with SMI. A closer look at the barriers driving this challenge reveal that nearly half of psychiatrists cite, unaided, patient psychological or cognitive issues as the main reasons for nonadherence. Patients' lack of understanding or denial of their illness or the need for medication, and accessibility issues, are key barriers as well.

When given a list of items that might possibly help patients with SMI remain adherent to their medications, almost all psychiatrists find the suggestions helpful. However, differentiation emerges when filtering by the things that would be *very* helpful—and two things rise to the top (see below):

Possible Ways to Improve Adherence



Questions 3-6: Now I'm going to read you a list of things that can possibly help patients with SMI remain adherent to their medications. For each one, please tell me if it is very helpful, somewhat helpful, not very helpful, or not helpful at all in helping patients with serious mental illness remain adherent to their medications. The first one is

Psychiatrists share that following up with patients to ensure compliance and speaking to patients about the importance of remaining adherent are two of the most helpful ways to improve medication adherence among their SMI patient population.

Utilization and Administration of LAIs

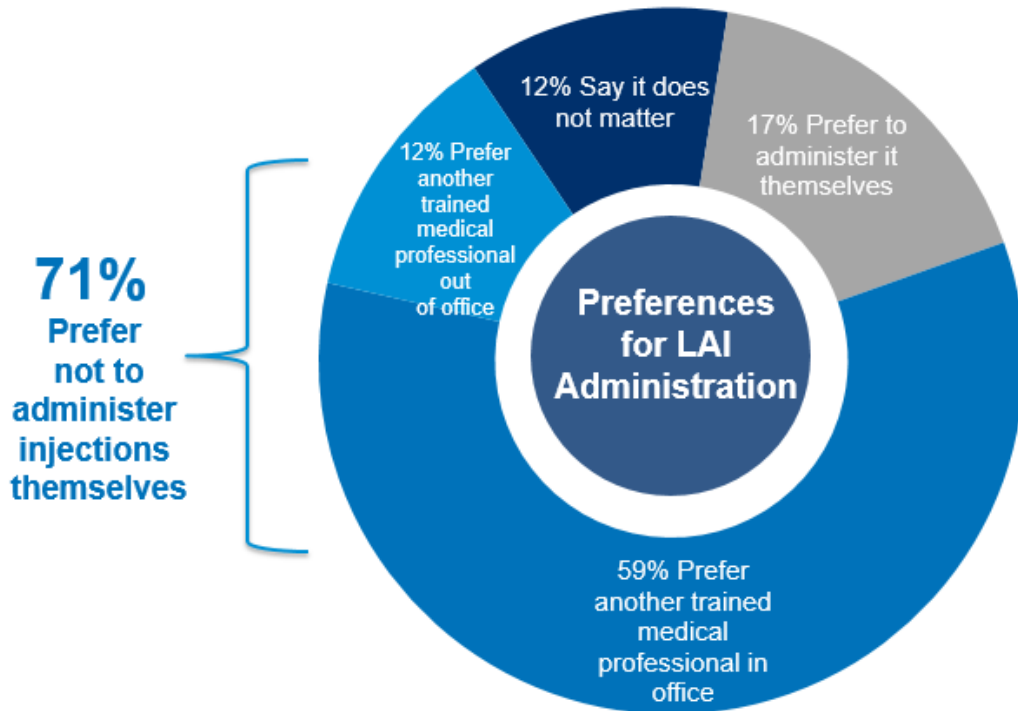
Next, the survey explored psychiatrist prescription of LAIs for patients living with SMI. Psychiatrists reveal that they have treated about 22% of SMI patients nationally with LAIs in the past 5 years.

Psychiatrists perceive that barriers to LAI adherence mirror barriers to medication adherence in general—with psychological and accessibility issues rising to the top at 46% and 44%, respectively. Additionally, 37% of psychiatrists mention that the injection itself holds many patients back, either from fear, injection pain, or a preference for oral medication. Similar themes emerge when psychiatrists are provided with a list of possible barriers. Fear, forgetfulness, and inconvenience are the top perceived barriers to patient LAI adherence.

Nearly all psychiatrists believe that facility convenience is important to facilitating patient LAI adherence. Aided, 91% acknowledge that patients do not have a convenient way to get to their doctor's or psychiatrist's office, where LAIs are often administered.

On the administration side, access and affordability issues (42%) rise to the top of psychiatrist-noted challenges to LAI administration. These issues include lack of time (14%), lack of staff (7%), and the patient cost (12%). Patient compliance issues also factor in (26%), as do logistical issues (20%), including capacity to stock and store medications, and injection-specific issues (10%).

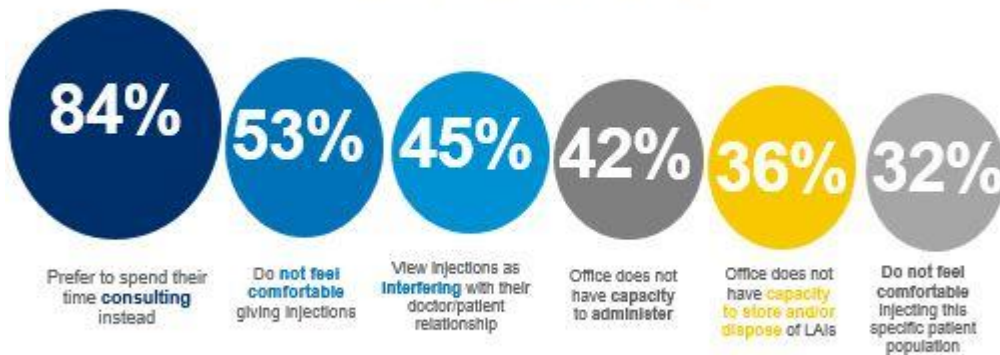
Additionally, about 7 in 10 psychiatrists say they prefer not to administer the LAI themselves. Only 17% of the surveyed population specifically say they prefer to administer (see below):



Q15. If you, personally, were to diagnose and prescribe an LAI to a patient, and assuming you had the following options available to you, would you prefer to administer the LAI to the patient yourself, prefer to have another trained medical professional in your office do it, have another trained medical professional outside your office do it, or does it not matter to you?

Among the seven in ten doctors who prefer to delegate their authority to another medical professional, 84% state it is because they prefer to spend more time consulting with their patients. While that is the main reason, other reasons are also compelling (see below):

Reasons for Delegation Preference
(among the 71% of psychiatrists who prefer another medical professional to administer)

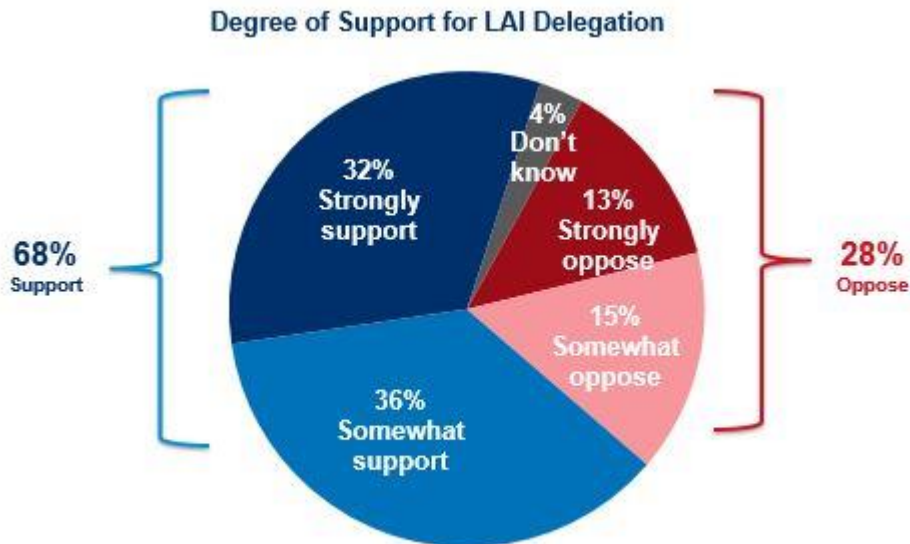


QUESTIONS 16-21: For what reasons would you prefer to have another person administer the LAI? I'll read a list--for each, please just answer yes or no.

Attitudes About Pharmacist-Administered LAIs

More than half of psychiatrists surveyed (52%) are unsure whether their state allows them to delegate authority to appropriately trained pharmacists to administer injections.

Before exposure to any reasons in favor or in opposition of this topic, the large majority of psychiatrists (68%) say they support having the option to delegate their authority to administer LAIs to appropriately trained pharmacists (see below):



QUESTION 24: Do you strongly support, somewhat support, somewhat oppose, or strongly oppose giving psychiatrists the option to delegate their authority to administer an LAI to an appropriately trained pharmacist?

Unaided, almost half of supporters highlight the convenience of delegation, while the top reason cited for lack of support reveals skepticism of whether that role would be appropriate for pharmacists to play (see below):

Reasons for Support

46% Convenience may help improve adherence

- 27% More facilities are/will be available
- 8% Increased convenience for patients (general)
- 5% Increase medication adherence

18% Capable and supportive

- 15% Trained pharmacists are capable
- 3% Would provide more support to staff

"They already provide vaccinations against flu, etc. making it reasonable to conduct trials, so I think if you have someone able to perform LAIs, we can give it a try."

"This option will be very useful for the patients as this will increase their chances of getting LAIs and will reduce chances of patients missing appointments."

Reasons for Lack of Support

26% Not appropriate role

- 8% Pharmacists are not trained
- 7% Pharmacists not equipped for adverse reactions
- 8% Trained nurses do injections already

8% Patient care

- 4% Psychiatrist needs to monitor
- 3% Psychiatrists know patients

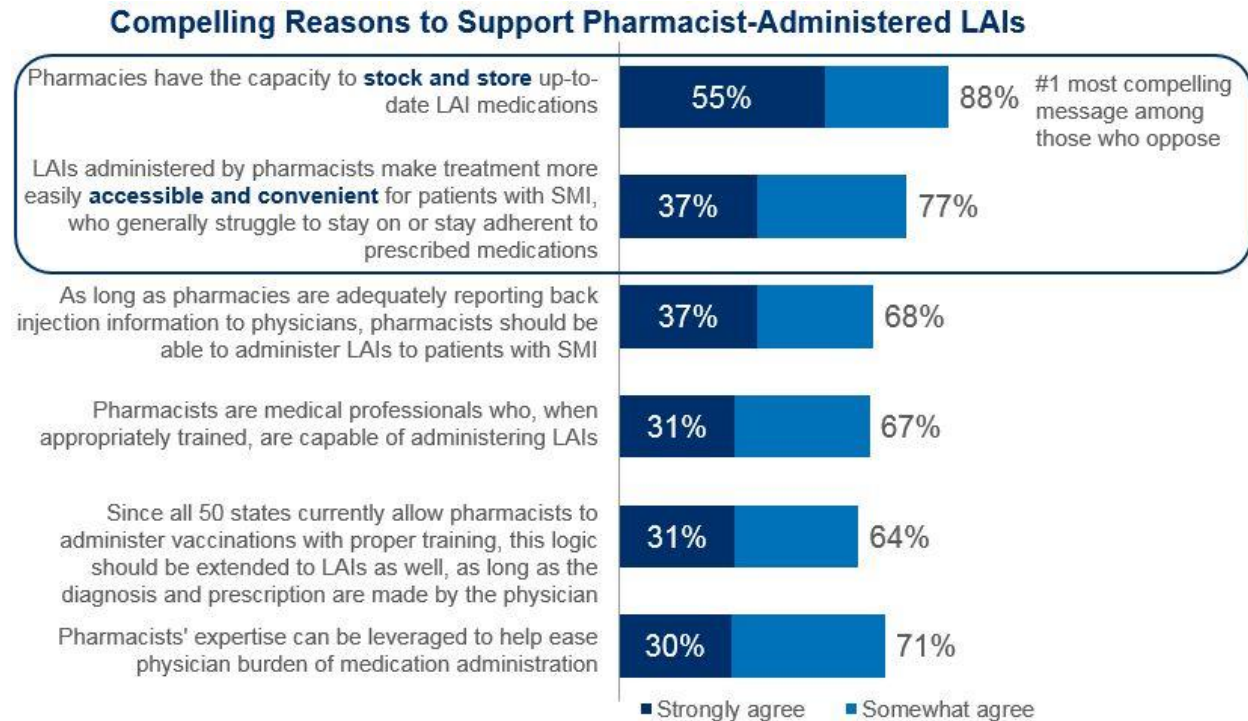
"Ideally nurses are the staff members [that are] supposed to perform this and I think they do it better."

"Because some LAIs require special monitoring for which the pharmacists are not trained. They just cannot cater to that need."

Following unaided impressions, psychiatrists were shown a set of reasons for why appropriately trained pharmacists should be allowed to administer physician-prescribed LAIs and a set of reasons for why

they should not be allowed. The order in which the sets were shown across our respondent population were randomized to accurately account for order bias.

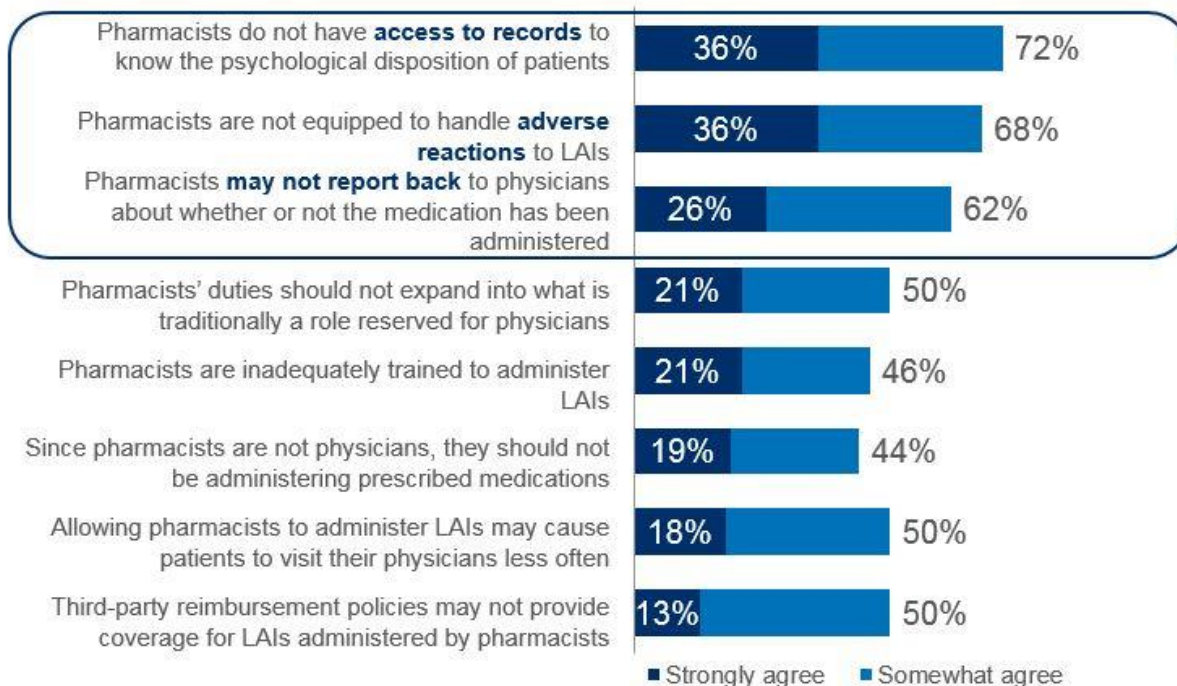
Among the reasons to support pharmacist-administered LAIs, pharmacist capacity to stock and store LAI medication rises to the top—with 88% of psychiatrist agreement. This is also the most compelling reason among those who initially opposed the idea. Accessibility and convenience, at 77%, is the next most compelling reason. Both of these key benefits directly align with and address the unaided adherence barriers previously mentioned. The graph below illustrates the full list of benefits:



QUESTIONS 26-31: I'm going to read you a list of reasons some people have given as to why appropriately trained pharmacists SHOULD be allowed to administer physician-prescribed LAIs. Please tell me how much you agree with each one - do you strongly agree, somewhat agree, somewhat disagree, or strongly disagree?

For reasons to oppose the option to delegate, top concerns include the lack of pharmacist access to patient records (72%) and the perception that pharmacists may be ill equipped to handle adverse reactions to LAIs (68%). The graph below illustrates the full list of concerns:

Compelling Reasons to Oppose Pharmacist-Administered LAIs



Q33-Q40. I'm going to read you a list of reasons some people have given as to why appropriately trained pharmacists should NOT be allowed to administer physician-prescribed LAIs. Please tell me how much you agree with each one - do you strongly agree, somewhat agree, somewhat disagree, or strongly disagree?

Following exploration of reasons, overall support for pharmacist-administered LAIs remained the same—68% of psychiatrists were in support prior to hearing reasons and 68% were in support after hearing reasons. Only 10 psychiatrists, in total, changed their mind after hearing both sets of reasons.

Bottom line—even after exposure to points of opposition, there is still majority support of pharmacist-administered LAIs.

Policy Considerations

Policies that give physicians the option to delegate medication administration to pharmacists for physician-prescribed LAIs to patients with SMI offer several advantages:

- Convenience – Transportation can be a barrier to many patients with SMI, but most individuals in the United States live within five miles of a pharmacy.^{10,11,12}
- Comfort with pharmacies – Most individuals (91%) taking mental health medication are very comfortable going to community pharmacies to fill their medications.¹³
- May increase medication adherence – About 50% of individuals with SMI miss doses of medication, which increases the risk of symptom relapse.^{14,15,16} However, some pharmacy-based intervention services have shown positive impact on medication adherence for individuals with SMI.¹⁷

To help improve patient access and LAI medication adherence, policies may consider the following:

- Recognize retail pharmacies as alternate LAI administration sites.
- Encourage coordinated care and communication between physicians and pharmacists.
- Require appropriate pharmacist training for administering prescribed injections.

Sample Protocol

The number of interviews conducted in each state was apportioned within the sample of 200 to reflect the actual proportion of psychiatrists in each state. The ratio of psychiatrists per state to the number of psychiatrists included in the sample per state* is as follows¹⁸:

Alabama: 440:5	Georgia: 410:3	Maryland: 610:5	New Jersey: 740:6	South Carolina: 240:3
Alaska: 40:0	Hawaii: 200:2	Massachusetts: 890:7	New Mexico: 150:1	South Dakota: 40:0
Arizona: 590:5	Idaho: n/a:2	Michigan: 700:6	New York: 3,110:26	Tennessee: 190:2
Arkansas: 320:3	Illinois: 1,000:8	Minnesota: 380:3	North Carolina: 570:5	Texas: 880:7
California: 3,160:25	Indiana: 270:2	Mississippi: 90:1	North Dakota: 80:1	Utah: 190:2
Colorado: 450:4	Iowa: 90:1	Missouri: 420:4	Ohio: 1,140:10	Vermont: 120:1
Connecticut: 800:7	Kansas: 160:1	Montana: 140:1	Oklahoma: 260:2	Virginia: 750:6
Delaware: 120:1	Kentucky: 180:2	Nebraska: 100:1	Oregon: 360:3	Washington: 310:3
District of Columbia: 240:2	Louisiana: 130:1	Nevada: 40:0	Pennsylvania: 940:8	West Virginia: 140:1
Florida: 790:7	Maine: 210:2	New Hampshire: 70:1	Rhode Island: 360:3	Wisconsin: 330:3
				Wyoming: 40:0

*Data for Idaho not available.

¹ United States Department of Health and Human Services. Substance Abuse and Mental Health Services Administration. Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health. <https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>. Accessed February 7, 2018.

² United States Department of Health and Human Services. Substance Abuse and Mental Health Services Administration. Mental and Substance Use Disorders. <https://www.samhsa.gov/disorders>. Accessed February 7, 2018.

³ United States Census Bureau. QuickFacts. United States. <https://www.census.gov/quickfacts/fact/table/US/AGE295216#viewtop>. Accessed February 5, 2018.

⁴ Perala J, Suvisaari J, Saarni S, et al. Lifetime Prevalence of Psychotic and Bipolar I Disorders in a General Population. *Arch Gen Psychiatry*. 2007;64:19-28.

⁵ United States Department of Labor, Bureau of Labor Statistics. Occupational Employment Statistics. Occupational Employment and Wages, May 2016. 29-1066 Psychiatrists. <https://www.bls.gov/oes/current/oes291066.htm>. Accessed Dec. 13, 2017.

⁶ Petterson SM, Liaw WR, Tran C, et al. Estimating the Residency Expansion Required to Avoid Projected Primary Care Physician Shortages by 2035. *Annals of Family Medicine*. 2015;13:107-114. <http://www.annfam.org/content/13/2/107.full.pdf+html>. Accessed on Jan. 11, 2018.

⁷ United States Department of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook. Pharmacists. Work Environment. <https://www.bls.gov/ooh/healthcare/pharmacists.htm#tab-3>. Accessed on February 1, 2018.

⁸ United States Department of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook. Pharmacists. <https://www.bls.gov/ooh/healthcare/pharmacists.htm>. Accessed on Jan. 16, 2018.

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- ¹⁰ Herb M, Miller E, O'Hara A. A housing toolkit: Information to help the public mental health community meet the housing needs of people with mental illnesses. Arlington, VA: National Alliance on Mental Illness. <http://www.namiohio.org/images/publications/Publications/housingtoolkit.pdf>. Accessed on Jan. 11, 2018.
- ¹¹ U.S. Department of Transportation. 49 CFR 391.41(b)(9): Federal Motor Carrier Safety Regulations.
- ¹² Rx Impact. Community pharmacy fills gaps in access and affordability for patients, payers. National Association of Chain Drug Stores. March 2013. http://rximpact.nacds.org/pdfs/rximpact_0313.pdf. Accessed on Jan. 11, 2018.
- ¹³ College of Psychiatric and Neurologic Pharmacists Foundation and National Alliance on Mental Illness. Characterizing the relationship between individuals with mental health conditions and community pharmacists. http://cpnp.org/_docs/foundation/2012/nami-survey-report.pdf. Accessed on Jan. 11, 2018.
- ¹⁴ Byerly MJ, Nakonezny PA, Lescouflair E. Antipsychotic medication adherence in schizophrenia. *Psychiatr Clin North Am*. 2007;30(3):437-452.
- ¹⁵ DiBonaventura M, Gabriel S, Dupclay L, et al. A patient perspective of the impact of medication side effects on adherence: results of a cross sectional nationwide survey of patients with schizophrenia. *BMC Psychiatry*. 2012;12(20). <https://bmcp psychiatry.biomedcentral.com/articles/10.1186/1471-244X-12-20>. Accessed on Jan. 11, 2018.
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- ¹⁸ United States Department of Labor, Bureau of Labor Statistics. Occupational Employment Statistics. Occupational Employment and Wages, May 2015. 29-1066 Psychiatrists. <https://www.bls.gov/oes/2015/may/oes291066.htm>. Accessed January 16, 2018.