D. Main Section of the proposal

The purpose of this project is to improve health outcomes for treatment of tobacco dependence among the Arizona behavioral health population. This will be accomplished through three aims that are intended to improve the success rate of quitting tobacco in the targeted population.

Aim 1: Provider Training.
Increase the awareness of healthcare providers (primary care physicians, psychiatrists, and their immediate support staff) of the behavioral health-specific treatment resources available through the Arizona Smokers' Helpline (ASHLine). The primary mechanism of this aim is the education of providers in formally requesting the use of ASHLine's pharmacist services. A corollary of this training is that referrals to ASHLine's behavioral tobacco cessation services may also increase. Awareness and increased use of ASHLine's pharmacist services will be accomplished through the training of all psychiatrists, primary care physicians and supporting healthcare staff at each of four designated Magellan integrated health sites. After attending trainings detailing the procedure for making formal referrals to ASHLine and requesting pharmacist services, providers will make up to 200 requests for pharmacist services over twelve months.

Aim 2: Implement Pharmacist Services.
Implement routine pharmacist review of referred ASHLine client medical records, including recommendations regarding management of clients' medications and incorporating tobacco cessation medications. By reviewing records of clients with multiple chronic conditions who are taking numerous medications, pharmacists can identify potential interaction risks and make recommendations on any necessary modifications, additions, or reductions in medications. A pharmacist consult will also include assessment of over-the-counter medications, alternative substances (including illicit substance), and lifestyle substances, such as sugar and caffeine. The pharmacist may offer suggestions for the provider and/or client in the management of his/her medication regimen when adding tobacco cessation medications to that regimen. The goal of this aim is for the on-staff ASHLine pharmacist to review 200 client records and make recommendations aimed at providers and ASHLine's cessation counselors (Quit Counselors).

Aim 3: Implement Pharmacist Recommendations.
This aim is intended to have the healthcare providers review pharmacist recommendations and coordinate medication changes when considering the addition of quit tobacco medications. Ideally, this report could lead to decreased hesitancy in prescribing tobacco cessation medication on top of numerous other medications and/or improved medication adherence and management. A key element of this report will be identification of possible interactions in current medication regimens and future regimens with the addition of tobacco quit medications. Benefits to the client's overall health through increased likelihood of tobacco cessation, improved adherence, and a potential reduction in medication costs through prescription efficiency, make this aim particularly beneficial. The goal of this aim is to have

providers review 200 pharmacist reports and implement the included recommendations in their treatment decisions as appropriate.

Current Assessment of Need in Target Area:

It is well established that the mentally ill are almost twice as likely to smoke as are members of the general population (Chung et al., 2011; Rohde, Lewinsohn, Brown, Gau, & Kahler, 2003). The current clinical practice guidelines recommend that the mentally ill receive smoking cessation treatments, including drug treatments (Fiore, 2008). Furthermore, Piper et al. (2012) found that treatment for smoking cessation does not have a negative effect on the mental health of psychiatric patients and may in fact improve outcomes for depression and substance use. The authors conclude that clinicians should encourage their psychiatric patients to undergo tobacco cessation treatment. Pharmaceutical treatments, in particular, have been shown to be a very cost-effective means of achieving tobacco cessation (Cornuz, 2007).

Although the mentally ill are likely to smoke, and treatment programs are readily available, barriers to treatment still persist. One such barrier, discussed by Hall and Prochaska (2009), is the fact that primary care providers simply are not trained to intervene in tobacco cessation.

Increasing the awareness of integrated health providers of the behavioral health-specific treatment resources available through the ASHLine has the potential to vastly improve our impact on the mentally ill community. Chung et al. (2011) found that while primary care providers serving a homeless minority population in Los Angeles were hesitant to prescribe or adjust many psychiatric medications for their patients, they were amenable to using a pharmacist-run psychiatric medication management service for assistance in these matters. Lancaster, Silagy, and Fowler (2000) found that offering training to providers improved their ability to offer assistance in tobacco cessation.

The need for specialized services at the ASHLine is also well documented. While the program wide seven month quit rate averages around 36%, the seven month quit rate for clients reporting multiple chronic conditions was 30%. Furthermore, only 33% of behavioral health clients referred to the ASHLine used tobacco cessation medications, whereas 42% of non-behavioral health clients referred to the ASHLine used such medications. These findings come from standard ASHLine program data for usual care clients and those who received pharmacist services at the ASHLine as part of a CPPW grant. The pharmacist assessment generated from this project revealed that behavioral health clients were on an average of almost eight medications, with an average of over two of these having interactions. These clients had an average of over seven self-reported chronic health conditions. In addition to helping clients manage their medications, the pharmacist was able to integrate strategies for a healthy lifestyle and medication regimen from a tobacco cessation perspective. Considerable client feedback centered on the knowledge they received from pharmacist consultations and how such interactions help engage them in the quitting process. The profound success of standard ASHLine support in helping Arizonans quit tobacco is an excellent basis on which to introduce tailored treatment services for behavioral health patients using tobacco.

Technical Approach, Intervention Design and Methods:

This project entails training clinicians to use pharmacist services at the ASHLine. These services are aimed at helping providers make informed decisions regarding their patients' medication use. Ideally, such decisions will focus on prescribing tobacco cessation medication and other medication management components. With this increased medical and pharmaceutical support, behavioral health patients using tobacco are expected to increase their success rates in ASHLine's tobacco cessation program. Technical details of project implementation are broken down by aim and detailed below.

Aim 1: Provider Training.
ASHLine will work with Magellan to identify four suitable sites for participation in this project. Sites will be chosen based on capacity for making formal referrals to the ASHLine and previous collaboration. Clinicians from each participating site will attend trainings. These clinicians will be practitioners of primary care and psychiatry, as well as their support staff. Once sites and providers are selected, trainings will be scheduled and delivered by a member of the ASHLine Referral Development staff. This staff member will have experience in providing various ASHLine trainings and in-services to partnering organizations.

The training will detail three aspects of the pharmacist program at the ASHLine:

1. What pharmacist services are offered and how to use them (i.e., pharmacist report).
2. When to request the pharmacist services.
3. How to formally request the pharmacist services.

The first training item describes the function of the pharmacist at the ASHLine and what services she provides. The primary service is a report summarizing the patient's medication use and containing a recommendation regarding medication management. This recommendation is meant to alleviate any concern that a provider may have in prescribing tobacco cessation medication on top of other medications currently being taken by the patient. Other areas of recommendation are potential drug interactions, a potential reduction in medications prescribed, comments on medication adherence, etc.

The second item will outline instances of clients who present with at least two chronic health conditions, one being tobacco dependence and the other being a behavioral health problem. Since this population of patients is likely to be taking multiple medications, they are also likely to benefit from pharmacist intervention.

The third item will focus on integrating the request for pharmacist service into a section of the WebQuit referral program that is already in use by the provider and healthcare site. WebQuit is ASHLine's web-based interface that is used for referrals and data collection. At present, if a client discloses that they use tobacco, a process that requires the intake personnel to complete

a formal referral using the ASHLine WebQuit program is initiated. This program transfers client information to the ASHLine for ASHLine Enrollment Staff to proactively contact the client and, if they are interested, enroll them in ASHLine support services. Providers, during the training, will be instructed to request pharmacist services in the notes field of the referral form through a standard procedure. This request will activate a process for enrolling the patient into the ASHLine behavioral support program and engaging pharmacist services.

Aim 2: Implement Pharmacist Services.
Under the proposed plan, providers will be instructed to request a pharmacist consultation in the notes section of the WebQuit referral form. ASHLine Referral Call staff is currently tasked with reviewing incoming referrals and proactively calling clients to provide information about the program and, if they are amenable, enrolling them in counseling services. Referral Call staff will now be instructed to review the notes section and forward any enrolled clients who were referred with the request of pharmacist services to one of two ASHLine counselors who will be trained as pharmacist referral specialists, and the client will be flagged in ASHLine records as being a subject for this project. This designated ASHLine counselor will review the completed enrollment form and create a summary of relevant behavioral health conditions, medication history, and tobacco use history. The counselor will then conduct the medication and lifestyles questionnaire with the client. These data will be available to the pharmacist, who will conduct a thorough review of the collected data. The pharmacist will prepare a report with recommendations for medication adjustments related to the review, including explanations for those adjustments. Prior to the first referral, ASHLine will consult with the pharmacist regarding the required information that needs to be pulled from the enrollment form and sent to her. This completed summary will be forwarded to the pharmacist for formal review. The designated ASHLine counselor will be trained to extract specific information from the enrollment form to create the summary that will be used by the pharmacist.

Aim 3: Implement Pharmacist Recommendations.
Pharmacist services will include: medication review; lifestyle assessment; development of summary report, including potential drug interactions; medication adjustments or attention to treatment concerns; follow up consultation to assess behavioral changes and medication adherence; and consultation with ASHLine counselors regarding the client. The pharmacist will be provided with a summary of the client's information, along with the ASHLine enrollment form containing all demographic, tobacco use, and health history information. Although the pharmacist will not, as a matter of routine, speak directly with clients, the pharmacist may contact the client if clarification on any aspect is required. The pharmacist will review the client's background and medication use in order to make a recommendation to assist the client's physicians in making decisions regarding medications, including number of formulations, possible interactions, and, most importantly for the purposes of this proposal, how tobacco cessation medications might fit in with the client's regimen. If the client is not currently prescribed tobacco cessation medication, the pharmacist may suggest adding one to the client's regimen, depending on the client's current medical and mental status.

This report will be shared with the tobacco quit counselor, the client, and the prescribing physicians at the referral location. The provider can review the report to make direct changes, as necessary, to the client's medication and treatment course. The report will also be reviewed by the ASHLine quit counselor, who will use the report to discuss the recommendations directly with the client for client input. At the start of this project, the designated ASHLine counselor will receive training on how to use the pharmacist report when providing behavioral support services to his or her client.

Evaluation Design:

Evaluation for this project will consist of both process and outcomes measures. Where possible, links will be made between the two to reveal any mediating effects that process variables have on outcomes. Such knowledge will provide direction in deciding how to optimize outcomes. Data will come from surveys administered by ASHLine, the WebQuit online interface, and Magellan.

Evaluation for Aim 1: Training.
ASHLine uses an established survey when it delivers trainings and in-services. This survey, developed by ASHLine, measures the participants' knowledge obtained from and satisfaction of the event. The knowledge items for the present project will reflect the three aspects of pharmacist service detailed above: services offered and how to use them for decision making; technical procedure for requesting services; and under what circumstances to request services. This survey will be administered at the close of each training. Data from this survey will also allow us to make any adjustments in the training as needed.

Outcomes measures for the training aim will be on the number of providers who were trained and the number of sites where trainings were delivered. In addition, the number of provider requests for pharmacist services and the type of clients referred (behavioral health condition, comorbidities, medication use) will be obtained. These outcomes are intended to measure the effect of the training. Secondary outcomes measures will be the actual number of referrals (not just those requesting pharmacist services) from participating providers. This measure will estimate the effect of training in generating increased awareness or interest in referring behavioral health patients. Comparison with historical data from ASHLine will be used to help establish this relationship.

Evaluation for Aim 2: Implement Pharmacist Services.
Evaluating the request for pharmacist services will comprise data from providers, ASHLine staff, and the pharmacist. Process measures will focus on the ease and integration of the request procedure into the existing EHR and WebQuit referral programs. The process of ASHLine staff receiving the flagged client enrollment form and summarizing the essential information to be forwarded to the pharmacist will be evaluated. The pharmacist will then be asked whether she received the necessary information and if it was in the required format. The process of disseminating the report to both the provider and the quit counselor will be evaluated.

Effectiveness of mechanisms of dissemination and reception of this report, as well as the clarity and usefulness of the report content will comprise the evaluation measures.

Outcomes measures will include the number of number of reports that were created, disseminated, and received by the provider and the quit counselor. These numbers will be linked with the number of requests for pharmacist services to ensure that all demands were met.

Evaluation for Aim 3: Implement Pharmacist Recommendations.
The main evaluative component for this aim is whether and how the pharmacist report was used by the provider and quit counselor. Self-report surveys will be administered to the aforementioned targets of this report. The survey will focus primarily on the process variables of how the report was used. The content of the pharmacist report will also be used for evaluation. Content of interest in this report is primarily the pharmacist recommendations. These recommendations will be classified in terms of their relevance for decision-making. Examples include integration of tobacco cessation medication, reduction in number of medications currently used, potential medication interactions or lack thereof, etc. Counts of each recommendation type will be made, along with a survey given to the providers and quit counselors of the usefulness of these recommendations in decision making. Relationships between client medical characteristics (health problems and medication and tobacco use) and recommendations will also be evaluated.

A substantial evaluation of this aim will be on outcomes; namely, the results of the pharmacist recommendations. This aspect can be specified as what recommendations were implemented, and what was the effect of using these recommendations for the patient's health outcomes and tobacco use. For the report use by the providers, counts of the number of recommendations implemented in relation to the total number of recommendations made will be made from surveys of providers and aggregate data from client medical records. Furthermore, analysis will also focus on what types of recommendations are more likely to be used (prescribe cessation medication versus remove current medication). After a thorough evaluation of how the providers used the recommendations/report, an estimate of the effect of recommendation implementation will be made. Aggregate client records of health outcomes (specify what is available) will be compared with aggregates of the type and frequency of recommendations made. Furthermore, these data on implementation of recommendation will be compared with data on client activity within the ASHLine (quit tobacco, used medications, completed program, etc.).

Evaluation of the use of the report by the counselor will focus on trained/hypothesized interactions regarding the content of the report with the client. These interactions are expected to be: going over the report and what it means and why it was requested, generating strategies to align the report content with tobacco cessation, engaging the client by clarifying the role of medication management in promoting positive health outcomes, discussion proper adherence of medication, etc.

While the recommendations in the report are primarily intended to give confidence and knowledge to the healthcare provider, these individuals may not be using the report to directly work on or discuss tobacco cessation with the patient. The quit counselor, however, will attempt to integrate the report content into the counseling session and relate the information from the perspective and intention of quitting tobacco use. To formally evaluate the effect of the counselor's use of the report, we will provide this pharmacist report to half of the quit counselors. The other half of the participating quit counselors will not have access to the pharmacist report and will represent the treatment as usual condition. Program metrics (quit dates set, reduction in tobacco use, relapse frequency) will be compared between the two counselor groups to estimate the effect of using the report by the counselor to help the client quit tobacco.

Finally, clients will be surveyed for their awareness of the project and possible benefits (reduced cost, reduced stress, easier managing of medications). A brief health outcomes questionnaire will be administered to evaluate the effect of the ASHLine program and the implemented recommendation. Since patient level data will not be available from Magellan, surveying client health measures directly will allow us to more precisely link pharmacist services with real health and tobacco use outcomes.

Evaluation of ASHLine quit tobacco services:
Standard evaluation procedures that are currently integrated into and used by the ASHLine will be continued for this project. The ASHLine effectiveness data will be used as a mediating variable of the effect of provider referral on patient tobacco use. In-program data such as the number and duration of counseling sessions, number of quit attempts, days in program will be collected. Furthermore, program satisfaction and seven and 13 month follow-up surveys will also be made.

Analysis:
Overall, we expect to see that healthcare providers will implement pharmacist recommendations, when applicable. Specifically, a pharmacist assessment encouraging the use of tobacco cessation medication will result in healthcare providers writing more prescriptions for such medications. This increased use of tobacco cessation medication can, with the addition of ASHLine behavioral support services, promote a reduction in tobacco use and a resultant improvement in various health outcomes among Arizonans being treated for behavioral health conditions. This prediction will be tested by comparing many of the outcomes discussed above between clients at Magellan sites that participated in the training and those Magellan sites that did not participate. This quasi-experimental design is aimed at isolating the effect of pharmacist services in aiding providers' decisions in managing their clients' medications. Furthermore, the effects of implementing recommendations on patient health outcomes and cessation of tobacco use will also be evaluated. Mixed model designs will be used to control for site level variance, and additional predicted confounds, such as type of health insurance and tobacco usage, will be included in the statistical model. Linear models will be used when outcomes comprise continuous data, and generalized linear models will be used when outcomes comprise categorical data that are part of the exponential family of distributions.

Data sources:
Survey data will be collected on paper forms during trainings at Magellan healthcare facilities. All other self report survey data will be collected electronically with ASHLine's WebQuit system. This web-based interface presents the electronic questionnaire to surveyors, and allows them to enter the responses from the participants directly, in real time, into the ASHLine databases. WebQuit is also used to track the number, location, and attendees of each training. Furthermore, this program collects data on referrals, requests for pharmacist services, and client level data on enrollment information (demographics, tobacco and medication use) and progress through the ASHLine program (number of counseling sessions, relapses, reduction in tobacco use, etc.).

Data will be accessed with an ODBC connection to link a computer front end (SAS) to the Server on which the data reside. The authentication establishing this connection is encrypted. The ODBC connection, SAS front end, and Server have the following security elements in place to protect client data: an SSL certificate, discrete log-in measures for all users, roles assigned to each user based on his or her functions, and limited access to complete data sets. Additionally, data are housed in an independent server at The University of Arizona, Mel and Enid Zuckerman College of Public Health (MEZCOPH). Institutional security is provided at the site 24 hours a day whereas daily maintenance and backup is provided by MEZCOPH's independent informational technology team.

Health outcomes data from patient records at Magellan will be aggregated at the site level by Magellan staff, and these aggregate datasets will be forwarded to ASHLine for further analysis. Each sites' health outcomes will be assessed at baseline during the first 3 months of the project. A collaborative team of physicians will identify the primary health outcomes to report in aggregate related to both mental health and physical health outcomes. The outcomes may include number of hospitalizations for treatment of chronic mental or physical illnesses, self-reported symptoms related to chronic health conditions, and specific measures, such as change in blood pressure, blood sugar, BMI and others identified for the project. Baseline measures and reporting will be standardized at baseline across the four identified sites for the project.

Dissemination and Use:
The results of this project can be used to develop services that can help healthcare providers make more informed decisions regarding medication use and tobacco cessation. The primary service of this project comes from pharmacist review of client data and making recommendations to improve medication prescription and management. Findings from this project will be discussed and presented in reports and conference presentations. This dissemination plan is intended to bring awareness of the benefits of collaboration and pharmacist services to providers who can implement similar services in their organizations.

E. Detailed Work Plan and Deliverables Schedule:

Implementation of this project will be completed in three phases: development, implementation, and evaluation and dissemination. The development phase will comprise working with Magellan to identify participating intervention and control sites. This decision will be based on capacity and availability of staff participation. Conversations with Magellan will also focus on finalizing logistics for implementing the intervention. Development from the ASHLine side will consist of hiring and working with a pharmacist to establish the process for providing services. An ASHLine coach will also be selected at this time as the lead for making assessments of relevant client information that will then be forwarded to the pharmacist for review. The final area in the development phase is creation of the training program. The training will be structured by three primary aims: how to use pharmacist services, when to request pharmacist services, and how to formally request pharmacist services.

The implementation phase will begin by administering training to Magellan staff. As this training will detail the use of the ASHLine pharmacist, the formal request for services intervention can begin at the closure of each training. ASHLine staff will begin assessing background and other relevant information from referred clients and sending it to pharmacist. The pharmacist will review the file, make a formal recommendation regarding medication management, and forward this report to the client's provider(s).

The evaluation phase will consist of two components. The first evaluation will be concurrent with the development and implementation stages and will focus on identifying problems and implementing solutions. The second component will commence at the end of the intervention when all data are collected. This component will focus on characterizing the success of the project by reviewing outcomes measures and linking them to project goals. These data will be used to create a formal report in which conclusions regarding the project are discussed. The completion of this report will begin the dissemination component in which all participants and stakeholders are provided with information regarding the details of this project.

		Month		
		1-3	4-15	16-18
Development	IRB approval			
	Identify participating sites			
	Develop collaboration process			
	Hire pharmacist			
	Pharmacist service development (request process, report content, reception and dissemination process, etc.)			
	Identify participating ASHLine staff			
	Develop training			
	Program databases			
Implementation	Implement training			
	Magellan provider			
	ASHLine staff			
	Pharmacist services available			
	Conclude intervention			
Evaluation and Dissemination	Evaluation			
	Monitoring/process			
	Provider surveys			
	Client surveys			
	Analysis			
	Dissemination			