# Improving the Health of South Dakotans through the Prevention and Management of Diabetes, Heart Disease, and Stroke

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# 1) Brief

In spring 2018, the Centers for Disease Control (CDC) released a call to action to address health disparities among Americans with diabetes, heart disease, and stroke through CDC-1815. In response, faculty and staff at the South Dakota State University (SDSU) College of Pharmacy and Allied Health Professions and the South Dakota Department of Health (DOH) collaborated to create a five-year plan to identify barriers and develop viable solutions to improve the care of South Dakotans with diabetes, heart disease, and stroke as it relates to medication therapy management and pharmacy's role in patient care.

This report details Year One of the five-year project and focuses on gaining a better understanding of barriers and facilitators that impact prevention and management of diabetes, heart disease, and stroke. Patients, practitioners, payers, and other individuals or organizations that can help facilitate communication or billing and reimbursement were recruited for this project. Year One will serve as a building block for the remaining four years of the project, by identifying the successes and challenges of healthcare provision silos of care, and reimbursement.

Recruitment for the project was done via newspaper, mailings, posters, social media, and word-of-mouth. In total, 50 patients, 69 practitioners, and 8 payer/others participated in Year One of the project. These participants were either selected to speak one-on-one with the project team (referred to as elicitation interview) or in a focus group setting. There was a diverse representation within the three stakeholder groups; however, due to time constraints, the project team was unable to focus on recruiting American Indian participants, South Dakota's largest minority group which comprises approximately 9% of the state's population.

Year One provided rich information and insight from multiple perspectives on managing diabetes, heart disease, and stroke. A recurring theme from all three groups was the lack of awareness of medication therapy management (MTM) and the other services that pharmacists could provide. However, there was consensus that pharmacists are in an ideal position to fill the gaps that were identified.

Subsequent years of the project will build off the foundational information that was gained through the focus groups and interviews conducted in Year One. Recommendations from each group's perspective were pulled from a robust qualitative analysis. Project gaps that were identified in Year One will be filled in the subsequent years.

Year One of the project further justified the need for pharmacists to fill the holes in patient care when it comes to the management of chronic diseases.

## 2) Background

Every year, an estimated 5,000 people in SD are diagnosed with diabetes, and 21,000 more people have diabetes but are undiagnosed (American Diabetes Association [ADA], n.d.). This accounts for 8% of SD adults diagnosed with diabetes, though this increases to 16% in the American Indian population (South Dakota Department of Health [SD DOH], 2018). Additionally, heart disease is the second leading cause of death in SD, while stroke is the sixth leading cause (Hoyert, 2012; South Dakota Department of Health, 2017). The prevalence of cardiovascular disease (CVD) not only affects overall health status but also impacts economic outcomes. In 2012, the estimated annual cost of CVD was \$981 million in South Dakota. Also, the geographical layout of South Dakota contributes to the health disparities in the state. Thirty of SD's 66 counties (45%) are designated as rural (less than 36 people per square mile) and 34 (52%) are considered frontier (less than six people per square mile). In comparison, only 18% of the United States' total population lives in a rural area (United States Department of Agriculture [USDA], 2015).

To see a primary care provider (PCP), it is not uncommon for rural patients to travel more than 50 miles (SD DOH, 2018). Results of a recent survey of older adults in the region of North Dakota, South Dakota, Montana, and Wyoming indicated that the average distance for patients to travel to a routine healthcare appointment for management of their chronic diseases is 42 miles, though the distance overall varies from blocks to over 100 miles (Mattson, 2010). Given these challenges, community pharmacies may represent an underutilized setting for patients to receive health services, especially in areas where traditional healthcare facilities are not available. It is estimated that 64% of SD residents live within a 15-minute drive to a pharmacy, and 81% are within a 30-minute drive (Sehr, Miller, & Pugsley, n.d.). Given their expertise in medication knowledge and appropriate use, pharmacists can improve patient access to healthcare through provision of clinical services such as immunization administration, Medication Therapy Management (MTM) services, disease state management, diabetes education, and point-of-care testing.

Medication Therapy Management services are structured in a variety of ways, but generally involve either targeted interventions or comprehensive review of all aspects of a patient's current medication use. Multiyear studies of MTM service models have shown positive impacts to patient health outcomes, reduced healthcare costs, increased medication adherence, and increased quality of life; thus, justifying further exploration into routine and widespread MTM implementation (Pellegrin, Krenk, & Oaks, 2017; Surbhi, Munshi, Bell, & Bailey, 2016; Matzke, Williams, & Moczygemba, 2016; Matzke, Czar, & Lee, 2016; Pinto, Kumar, Partha, & Becthol, 2014; Pinto, Bechtol, & Partha, 2012). Notably, in cases where MTM has been implemented, A1c levels in patients with diabetes decreased along with reductions

in systolic and diastolic blood pressures (Pinto, Kumar, Partha, & Bechtol, 2013; Pinto, Kumar, Partha, & Bechtol, 2014). Since MTM services can require a considerable amount of time to complete for both patients and pharmacists, MTM services were not routinely provided by pharmacies in a structured manner until the Centers for Medicare and Medicaid Services (CMS) enacted the Medicare Prescription Drug, Improvement, and Modernization Act in 2003, which required plan sponsors to offer MTM services to eligible beneficiaries. Following CMS' example, other private insurance providers, third party payers, and self-insured employers have also offered reimbursement to pharmacists for providing these MTM services to their beneficiaries. Empowering and educating patients on their medications helps decrease the issues associated with nonadherence, such as increased healthcare costs, poor medical outcomes, higher hospitalization rates, and greater insurance premiums (Sehr, Miller, & Pugsley, n.d.; DiMatteo, Giordani, & H.S., 2002; Sokol, McGuigan, & Verbrugge, 2005).

*Project Timeline:* This report details Year One of the five-year project. For reference, the timeline is as follows:

<u>Year 1:</u> SDSU will conduct a landscape analysis performed at three levels: patient, practitioner, and payer/others. This will include but is not be limited to: stakeholder identification, access pathways, current practices, roles, needs assessment, community asset mapping, and barriers and facilitators to care.

<u>Year 2:</u> Information collected from Year One will be used to inform strategic pathways in Year Two. This year will focus heavily on development by educating and engaging the patient, practitioner, and payer/others groups on the creation of a community-based practice model of care.

<u>Year 3:</u> This year will focus on implementation, mainly by adopting and adapting programs developed in Year Two.

<u>Year 4:</u> This year will consist of continuous quality improvement, modifying things that didn't work, expanding on things that did work, and evaluating program development by examining pre-determined evaluative metrics.

<u>Year 5:</u> The focus of this year will be on evaluation and dissemination. SDSU will complete evaluation from all the sites and assess sustainability needs and successful payment models. Practitioners, patients, and other stakeholders will be trained on these future payment models. While dissemination of interim and yearly reports will occur during the course of the 5-year period, a key emphasis area during the last year will be to share our experiences and

lessons learned with other states and organizations across the country and perhaps even internationally.

# 3) Methods

The South Dakota State University (SDSU) Institutional Review Board (IRB) provided approval of the project (Appendices F and G). Three main stakeholder groups participated in the landscape analysis for Year One. Participants were recruited from various parts of SD including Vermillion, Yankton, Rapid City, Spearfish, Pierre, Mitchell, Brookings, Watertown, Parker, and Sioux Falls. Each group was further broken down as follows:

- 1. Patient Groups:
  - a) Patients with metabolic syndrome
  - b) Patients with diabetes
  - c) Patients with CVD
- 2. <u>Practitioner Groups:</u>
  - a) Physicians (specialists and general practitioners)
  - b) Physician Assistants
  - c) Nurses
  - d) Pharmacists
  - e) Certified Diabetes Educators
  - f) Dietitians/Nutritional Therapists
- 3. <u>Payer/Others Groups:</u> These included Third-Party Payers and Selfinsured Employers within the state and other individuals/organizations that could help facilitate communication or billing and reimbursement.

# Recruitment & Enrollment

Patient recruitment was completed through a variety of approaches to facilitate a wide reach across the state of South Dakota. Social media such as Facebook pop-ups, classified ads in local newspapers, advertisements on the SD Department of Health Facebook page, flyers, and poster stands were used to recruit patient participants (Appendices A-D). The recruitment process for patients required that interested individuals call the advertised office phone number and speak to a member of the project team. A team member then screened patients and enrolled them in the project if they met eligibility requirements.

Recruitment of practitioners focused on those who currently have an active practice in SD caring for patients with diabetes, heart disease, and stroke. The project team contracted with Connect US Health and through them, Eagle One, to conduct recruitment efforts for practitioners. Participants were screened for eligibility and recruited via phone calls by Connect US Health staff. A list of the interested practitioners who were assigned to interview sessions was sent to the project team. A team member then sent more information about the assigned sessions to the participants, as well as reminder emails within a 24-hour time frame prior to the session.

For the final stakeholder group, organizations recruited included third-party payers, self-insured employers, and other groups that help facilitate communication or billing and reimbursement related to the provision of healthcare services. Administrators and other key decision makers of these organizations were recruited. The project team also created a list of potential payers through a web search and outreach through practitioner referral.

Interview types were divided into two categories: <u>elicitation interviews (EIs)</u> and <u>focus group (FG) sessions</u>. Participants could either be scheduled for elicitation interviews or focus group sessions, but not both. For patients, interested participants were first asked if they were comfortable sharing their thoughts in a group setting. If so, they were assigned to a focus group session. If not comfortable in the group setting, they were assigned to an individual elicitation interview. For the two other stakeholder groups, focus group participation was largely based on the individual participant's availability for upcoming scheduled focus group sessions. If the participant was unable to join an upcoming focus group, an elicitation interview was scheduled instead.

### Data Collection

#### **Elicitation Interviews:**

Two project team members were present during each elicitation interview: the facilitator and the assistant. The facilitator conducted the interview and moderated participant responses, and the assistant operated recording equipment and took additional notes during the session on nonverbal behaviors as well as other elements that may not be represented in an audio recording. For participants unable to meet in person, the interviews were conducted via Zoom with audio recording (only for participants in the practitioner and payer/others groups). Zoom is a secure video and audioconferencing software tool licensed for use by South Dakota State University. While no video was recorded, all sessions required the participant to be

available via video. This was to minimize variation among the face-to-face and Zoom EI sessions. Elicitation interviews were scheduled for 60-90 minutes. At least two recording devices were used to collect audio data for each interview and focus group. For face-to-face interviews, the audio was recorded either by handheld audio recorders, iPads, or both. For virtual interviews, Zoom recording functionality was used as the primary audio recorder, and a secondary handheld audio recorder or iPad was used as a backup. Each interview began with team members reminding participants of the project purpose and reading the informed consent form.

#### Focus Groups:

Three members of the project team were on site for each of the focus group sessions. The facilitator conducted the interview, the assistant operated the equipment and took additional notes during the session on nonverbal behaviors as well as other elements that may not be represented in an audio recording, and the standby coordinated food and drinks for the session break as well as directed participants to the appropriate location at the site. Food and drinks for these sessions were supplied by Dr. Pinto's lab funds and not the project funds. Participants were informed that the focus group sessions would last around three hours, including check-in time and time for breaks. Participants were encouraged throughout the focus group to elaborate on topics and were provided follow-up question prompts to help them in this process. There were three main categories of focus groups: pharmacist, mixed practitioner (registered nurses, dietitians, physicians, physician assistants), payer/others, and patient. Focus group dates, locations, and other initial scheduling details were provided to participants approximately 1-2 weeks before the session. Reminder emails were sent a few days prior to the scheduled sessions.

### Data Storage

The collected audio data was uploaded and stored on secure servers for transcription at a later date with assistance from the SDSU IT department. These computers housed two folders on Box, a secured internal SDSU cloud-based system, that were created for this project. One folder was accessible to all the project team members and contained project forms, interview packages, and additional general information related to the landscape analysis. The second folder was accessible only to the principal and co-investigators and research assistant (RA), as it contained participant-related material such as audio files from interviews and participant contact information.

After the interview, the RA uploaded the audio file into the principal investigator's folder on Box. The interview was then de-identified by the RA and sent to an assigned team member to transcribe the audio file using a word document. Once the transcription was complete, the transcribed files were stored on Box. Ten percent of the transcriptions were audited, and each team member performing transcription had at least one of their transcripts audited. The auditing process required a second team member to listen to the audio recordings of interviews and follow along with the transcripts while identifying missing words and concepts using track changes. The audit document was uploaded in Box. Any transcripts that had more than 30% of the total words changed in the audit compared with the original transcript were considered to have failed the audit process. This comparison was made with the 'Compare Documents' functionality in Microsoft Word. Transcripts that failed the audit process were deleted, and a third team member was assigned to create a new transcript based on the audio recording. Once complete, this new transcript was stored with the other transcripts on Box and could be audited again if selected among the 10% of transcripts that were audited. A small subset of interviews (n=6) were transcribed with NVivo. Per the South Dakota Board of Regents policy, all project data will be disposed of securely seven years after the end of the full project period. All electronic data will be downloaded from Box and provided to the IT security office at SDSU. The security office will destroy this data and will send the principal investigator (PI) verification confirming the secure destruction of the data. All hard copies will be shredded using a scrambled shredder.

#### Data Analysis

All transcripts were downloaded into NVivo using a specific computer designated for project-related work to facilitate additional analysis. NVivo v.12 (QSR International Pty Ltd. Version 12, 2018.) is software used for thematic analysis available through South Dakota State University. One of the co- investigators (Co-Is), an expert in qualitative analysis, created a codebook (Appendix E) to guide the project team in analyzing transcripts. In NVivo, project team members coded the transcripts and identified reoccurring themes. The transcribers, auditors, and other team members completing the thematic analysis were blinded to each other and at all stages of the process. Once the thematic analyses from assigned individual team members were completed, the Co-I combined all the individual analysis documents from Box to NVivo and generated a report to identify overall reoccurring themes in the

project. Descriptive statistics for each of the three stakeholder groups were calculated by team members using Microsoft Excel.

### 4) Results

### Intervention or Activities Implemented

SDSU conducted a landscape analysis performed at three levels: patient, practitioner, and payer/others. This included, but was not limited to: stakeholder identification, access pathways, current practices, roles, needs assessment, community asset mapping and barriers and facilitators to care.

### Approach

In total, 50 participants were enrolled in the Patient Group (PG). Qualitative and quantitative analysis methods were used to examine the PG data (Table 3 and 4). Participants represented many parts of the state, with more than half of the participants residing in rural communities (n=32). A variety of recruitment methods were used; almost half of the participants reported that they learned of the project through an ad in a newspaper (Table 1). Out of the 50 participants, 34 elected to take part in the EIs.

There was a total of 69 participants in the Practitioner Group (PrG). Participants in this group represented a variety of roles, including pharmacists (n=35), dietitians (n=11), advanced practice providers (APPs), which includes physician assistants, nurse practitioners, and nurses, (n=4), diabetes educators (n=5), and physicians (n=1). More than half of those in the PrG practiced in urban settings (n=39), with the rest practicing in rural areas throughout the state. Participants in this group also represented a variety of work settings, including clinics, in-patient hospitals, community health centers, health systems or integrated delivery networks, and independent and chain community pharmacies.

Table 1.	How Did Participants Hear
about the	e Project?

•	Ν
Newspaper	23
Mail	1
Word-of-mouth	11
Flyers, posters	10
Social media	2

Pharmacists were asked about the different services they offered to patients, including face-to-face consultation, medication reconciliation, medication synchronization, immunizations, and MTM. Out of the 35 pharmacists, most of them offered all of these services (n=18). Face-to-face consultations, medication reconciliation, and MTM were among the services offered by many of the pharmacists (Table 2).

Table 2. Services offered by Pharmacists

Service Offered		
Face-to-Face Consultation	25	
Medication Reconciliation	26	
Medication Synchronization	21	
Immunizations	20	
МТМ	26	

The third group consisted of representatives of one health plan, which is a large rural health regional integrated delivery network (IDN), with approximately 180,000 covered members in South Dakota and Iowa. Also present in this group were representatives of an organization through the South Dakota Department of Health that provides centralized repository for automatic upload of electronic health record information from 63 hospitals and 375 primary care clinics in the region that providers within the network can access to facilitate patient care provision. This was a smaller group (n=8) than the others but the data collected was no less robust. Participants in this group represented different roles within their respective organization, which allowed for well-rounded discussions.

# Effectiveness

**Patients:** A combined 179-page transcript of patient interview responses provided insights on overall patient perception of healthcare experiences for treatment of diabetes, heart disease, stroke, their precursors, and other comorbid conditions (Table 4). Patients were asked about what conditions they have been diagnosed with and if they take medications for these conditions. The majority of patients reported having a longstanding diagnosis (10 or more years) of Type 2 Diabetes (n=40) and most reported taking medications (n=34) to manage it. A smaller number of participants reported a history of stroke(s) (n=2), heart attack(s) (n=5), or heart failure (n=2). Many of the participants in the PG reported taking medications for high blood pressure (n=32) and high cholesterol (n=20). Time since diagnosis of the chronic conditions that patients reported ranged from as few as two years to 33 years.

When asked about the early signs or symptoms, respondents identified clear indicators and often, warnings from their healthcare providers of a condition that would require medical intervention. Patients also reported having a relatively normal existence living with at least one chronic condition; however, many of them reported struggling to maintain a healthy diet or lifestyle. Patients also found it, at times, difficult to become motivated to make positive changes to manage their symptoms

and stabilize the disease. A number of patients, especially those residing in rural areas, found it challenging to get to or even locate specialists, especially endocrinologists and cardiologists. When they could locate these specialists, it was not uncommon for them to find difficulty in actually physically getting to the providers. Patients also followed similar paths in their healthcare journeys and encounters (Figure 1).

Figure 1. Patient Healthcare Journey for Treatment of Diabetes, Heart Disease, and Stroke



The subset of the population approached was reflective of patients diagnosed with diabetes and CVD across the state. While we didn't target health outcomes in this year of the project, the information collected will lead to meaningful decisions about programming and eventual health outcomes. In regard to implementation, the findings from Year One will allow us to have specifically targeted and customized programming and educational interventions that will be helpful in implementing the previous initiatives outlined.

Table 3. Health Information for PG

Characteristic		
Reported diagnosis of diabetes	40	
Reported diagnosis of Type 2 Diabetes		
Reported diagnosis of Type 1 Diabetes		
Reported diagnosis of diabetes of unknown type		
Taking medications for diabetes		
Diagnosed with high blood pressure		
Taking medications for high blood pressure		
Diagnosed with high cholesterol		
Taking medications for high cholesterol		
Reported history of stroke(s)		
Reported history of heart attack(s)		

While exact details for the ages of the patients that were part of the project were not collected, many of them referenced Medicare and struggling to afford certain supplies associated with caring for their diabetes because they were on Medicare. One participant said that they "had a choice between food or medicine to treat their diabetes" because the medication was "hundreds of dollars," leading to disease complications and an eventual amputation. One patient (on private insurance) did not have money to pick up their blood pressure medication, leading to a week lapse in taking any medication. Due to this lapse, the patient had dangerously high blood pressures and was advised by pharmacy staff to seek medical care. Rich, thoughtful discussions in the PG focus groups and interviews provided, perhaps, the most impactful view of the state of healthcare in SD. Patients revealed stories that detailed their struggles and successes in managing their conditions, showing the true need for change. Many of the patients with cardiovascular disease, reported not getting enough education about the causes, symptoms, and lifestyle changes they could make to improve their quality of life. While we outlined quotes in a table below that provided a glimpse into the qualitative analysis, there are so many more meaningful words that we want to share from patients about their disease management journey:

"I took six or seven statins when they finally found one that would work right."

"I was a kid, though. Oh, well I just didn't pay attention to the doctor and it got worse."

"Every time I get a new medication I'll call her cuz I trust her and stuff and she'll tell me well, you can do this and this and this and this and your pharmacist can help you a lot."

"Um, yea I think when I was very first diagnosed I was- I felt like I was floating all by myself more or less, unfortunately, But, also, I have to take responsibility and I was in pure denial about it too. I was not happy about it so, if I ignored it it would go away. Which of course never works, but I mean I think I got pretty fair care even though I was resistant. I could've understood things a whole lot better, you know?"

"And then getting diabetic supply and the test strips are what's so –is what's so expensive for us. And stuff. And when you're on Medicare, there's –and you try to get them and stuff, you might as well forget it. If you can't get your test strips then... And how are you going to take care of your diabetes if you can't get the things you need and your insurance, especially Medicare, they won't help furnish-try to furnish any kind of, uh, test strips or anything like that."

"Um, I guess the doctors always talks about exercise and I have arthritis so bad in my knees and hips that it's like, sure, sure I'll exercise and I –it hurts to take any steps and all, so...You know, they don't seem to understand and so..."

"I think they need to be allowed more time with individual patients. You know, the scheduling people every 10 to 15 minutes, especially adults, well who have multiple issues. I just think that's not quite right and not to anybody's benefit."

"Stigma, most people don't really understand it I just tend to not even mention it since people misunderstand it. They think diabetes or you just ate too many sweets when you were a kid or you're just lazy. So, I don't even bring it up. Sometimes work it's better not to mention it."

"I didn't really know I had high blood pressure. I just got that heart attack."

"They talked about getting it (high blood pressure and high cholesterol) under control. But other than that, they just didn't seem too concerned."

# **Table 4.** Summary of Qualitative Results from NVivo Analysis

		Patient Perspective
Categories	Code	Quotes
The disease diagnosis experience	Prompts to seek care/Warning signs/symptoms/Screen	"had a cold, I didn't feel well, I was in school and I went home early. And my mother's a nurse, and at that time she worked in a clinicmy pressure was abnormally high"
	ings	"have Crohn's disease, so my blood sugars get checked regularly and mine kept creeping up" "went to do one of those DOT physical (Uhm.) over ten probably about twelve years ago now (Ok.) and I was kicking out the blood sugar (Uhm, mhmm.) so I didn't believe it was right, so I says, "well, it's just due to all of the pop"
		"So they told me my blood pressure was higher than normal and they were worried about subsequent issues off that, with my kidneys or my liver or any of that. So they did some follow-up stuff, they did an ultrasound to make sure everything was ok and um then they just got me started on a medication "
		No, I haven't, um I'm a firefighter, so I have to get a chest x-ray every year, and they do a 12 lead and there's always labs, and they do a liver function test and everything and as far as I'm aware of there's never been any complications.
		"I couldn't breathe [you did] yeah. I was wheezing and I could not breathe, and when I went, well I went to [hospital] got a check, I mean. And they put me in the hospital for 4 days."
	Time since diagnosis	"was a sophomore in high school. So that would have been 2001, so 18 years" "about 8 years" ""
		"Yeah, and I've been dealing with [Crohn's disease] it for 20 years"
	Specialists seen	"Nope, no so I've seen a specialist for pulmonology, with my asthma and my allergies" "just an OBGYN when I had my tubes tied. And then, I have an optometrist central retinal vein occlusion with macular edema of the left eye. So I have been getting injections in my left eye" "endocrinologists"

Co-morbid conditions	" Crohn's Disease, glaucoma, asthma, a congenital heart defect, pulmonary hypertension, gastroparesis, anxiety, thyroid disease "
Self-care	"Once I started kinda taking my own shots or giving my own shots and things like that I was probably 6 or 7 Um, and just from repetition andolder siblings and peer pressure from them to grow up and do it on your own so mom and dad could go and do other things, so it was probably about 7 or so when I started giving myself my own shots and maybe 6 or so when I was checking my own blood sugar by myself"
Life impact of disease(s)	"taking better care of self"
	"exhausted all the time. Had to quit my nine to five career. Umm I am a free-lance writer now so I write when I am awake but it has turned my world upside down"
	"yeah it's a struggle but yeah I mean I have a good support network"
Where care sought	"Hoven was so small. I mean it's a town of maybe 400 people at the time, so it was a very small hospital. They weren't equipped to handle me"
Access problems/issues	"they sent me to the, the class for nutrition and um, we talked about sugars and managing my weight [cost] was out of pocket"
Dosing (challenges)	"I believe the dose has been increased. I take now I take 20 mg per day, and I think I probably started at 5 or 10. I take 20 now, and it's been well controlled, I think"
Medication access	"with the company that I work for, we have to go through mail order, and so you would think I would be pretty on top of how much insulin I have, but sometimes you forget, you think you have an extra bottle, and then you're like, oh, you got to order it, so it's not just run down to the store to pick it up. So that's I guess the only hindrance slash barrier that I can really think of, is more companies are wanting you to go through mail order than just being able to walk into any pharmacy and pick it up when you need it"
	"one time they gave me the wrong one because we took it home, my husband picked it up, and they gave him the wrong one and [Oh] he looked at it and because we took it home, we couldn't take it back, so we had to pay for it"

		"Somehow my medication has got all screwed up so it does not come at the same time anymore, so it gets, I feel like I just call them and call them and call them"
		"So like say there's a family of four and I get a text saying that a prescription is ready but I wouldn't know who it was for, I would just get the script number and the price like you have the script number such and such ready and its \$10 but it won't say it's for my child you know, whatever"
		"Uh, Dr. X, uh, told me to go see Dr. X, uh he had a doctor in town here, but they wouldn't accept Medicare or Humana"
		"I'm on Medicare now and so the biggest struggle is the strips. They allow you three times a day and I test five to six times a day. I'm wanting to go with the patch thingBut getting the medicine's nothing. No problem"
The medication experience	Medication adherence/ medication management	"multiple medications. Now me, I just have the one I take in the morning and then I have the one I take in the evening. And I've done so for years and years and years now, so it's ingrained with me, but like a pill box, or little post it note, where you can track-on your refrigerator, or calendar-I've taken my AM meds, I took my PM meds. That type of stuff would be helpful. Just little memory aids, would be helpful"
		"umm I have a pill box. AM and PM, I fill them up every week. I take some when I get up and take some early afternoon and I take some at bed"
		"sugar levelsUh, I have, I have trouble keeping them, course, and when I was getting on cortisone, my blood sugar was sky-high"
	Where was care sought	"Initially I was taken to the Hoven Hospital and they referred me on to the Aberdeen hospital which then in turn referred me on to Children's Medical in Minnesota"
	Satisfaction with care	" I said my dad has high blood pressure and my grandma has high blood pressure. I have blood pressure and we need to treat this. And she said *sarcastically* yeah we need to treat it or you're going to stroke out. So that didn't feel really good having to push to get something so simple treated"

	Satisfaction with adequacy of diagnosis	" I'm feeling like I'm pretty good about staying ahead of the game on some of my stuff, but yeah I feel like it was adequate"
	Satisfaction with provider relationship/ trust	"Once you build a trust relationship you know, then they feel free to pick up the phone, but until they see you enough times and they know what you can offer them, I don't think they'll ever lean on you"
The healthcare service experience	Satisfaction with information provided	"I was, yeah, yeah, but I was relatively young, and I had my parents who were heavily involved, so they were doing a lot of that stuff, um"

Importantly, most patients that did report the presence of a chronic condition also reported taking medications. Barriers that patients reported were due to implementation of lifestyle changes that they could make to further manage their symptoms. Healthier eating and exercise were areas that patients knew they needed to improve in, but they lacked the motivation and support to carry through with those changes. Multiple patients mentioned either diabetes education groups or programs for their cardiovascular disease that they were told about, but also mentioned that the cost of the group outweighed the perceived benefit.

**Practitioners:** A combined 459-page transcript of provider interviews and focus groups offered an insider view into practice sites across the state and perceptions of barriers and facilitators to patient care for diabetes, heart disease, and related conditions (Figure 2). A number of providers identified the challenge of making healthcare and preventive services affordable to patients and working to find creative strategies to minimize out-of-pocket costs (Figure 3). In that regard, providers have a singular goal of minimizing the stress to the patient that may negatively influence disease status. The use of e-technologies has become an effective tool for managing patients' health status, facilitating communication among care providers, therefore promoting interprofessional, patient-centered team care. Participants in the PrG also discussed the various interactions they have during a patient's healthcare journey (Table 5).



### Figure 2. Summary of Themes from Qualitative Analysis





Table 5 Breakdown	ofvarious	nrovidar	ancountary with nationts
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Touchpoint	Initiate Care	Diagnose/ Treatment Plan/ Med. Prescribe	Referral/Ancillary Care Order (labs)	Med Fulfillment	Follow-up (In person)	Follow up (By Phone)	Progress Monitor/ Tracking (Record Review)	Advocacy	<b>Counseling</b> And/or <b>Education</b>	Supportive Care
Provider Type										
Primary Care	•	•	•		•	•	•			
Specialty <u>Practice</u> (Oncology, Endocrine., Cardio., etc.)	•	•	•		•					
Pharmacist				•	•	•	•			
Nurse					•	•	•	•		•
CDE/Nutriti on Specialist									•	
Patient Advocate								•		•
Social Worker								•	•	•
Clergy										•

# Provider Interaction/Communication

Providers in general report a collegial relationship and a relative understanding of each other's roles and responsibilities. The majority suggest that they find each member of the care team essential and experiences with the likes of certified dietary educators, community health workers, social workers, and others are vital to supporting continuity of care to make patient care experiences successful.

### <u>Relationship between Physicians, Advanced Practice Providers (APPs), and</u> <u>Pharmacists</u>

There is a strong desire to expand interdisciplinary collaboration among physicians, APPs, and pharmacists as well as a need to better understand the scope of practice and range of services offered by practitioners from various disciplines. In many practice sites, whether specialty or primary care focused, APPs are trained in a variety of aspects of care to complement the physician's role and take on a significant portion of the routine patient care load independently and often work side-by-side with the physician, particularly in small practice settings. The majority of practitioners express that they have positive relationships with APPs and pharmacists. One challenge acknowledged regarding APPs, specifically nurses, was the occasional turnover in already staff-strapped facilities—requiring recruitment and training of new staff along with the learning curve that accompanies the new hire. Pharmacists seek to demonstrate the expanded patient care role they could play.

### Interaction with Specialists

When asked about routine interactions with specialists, specifically cardiologists and endocrinologists, providers noted that often interactions may be inconsistent or seemingly at random if they do not work within the same practice sites where specialists are based.

### **Medication Therapy Management within Practice Sites**

Respondents were asked if Medication Therapy Management services were offered in their practice sites. A number of providers acknowledged that elements of MTM exist within their sites, however a lack of understanding persists. The ability to provide MTM services is not consistent across practice sites throughout South Dakota with practitioners citing lack of space, lack of education and training, and time constraints as barriers to this service. A number of respondents were not aware of the various aspects of MTM based on pharmacist scope of practice.

### Provider Receptivity to MTM Pharmacy Practice

Several providers agreed that fully implementing MTM services into their practice would be beneficial and also add a needed efficiency to their patient care. Others

expressed concerns that providers may believe their current service offerings are sufficient and MTM service implementation is unnecessary.

### **Electronic Medical Records**

Given the distance between practice sites, electronic medical record (EMR) interfacing was consistently mentioned as an important facilitator for team care, especially for smaller facilities that are not in close proximity to practice partners. Barriers such as dissimilar electronic medical records systems in facilities under the same health system, the lack of a highly accessible and updated state-wide EMR, minimal provider availability to document thoroughly within the EMR, and poor interprofessional communication may negatively impact patient care outcomes.

From a practitioner's perspective, there are numerous opportunities to improve the health of these patients. Those in the PrG were able to identify goals that they hoped they and their practice could achieve in the next five years (Figure 4). Appropriately, patient concerns and needs reiterated some of these goals. A number of rural providers expressed the need for more facility space specifically for the purpose of providing more of a one-stop experience where patients accessed a variety of services, i.e. MTM services, labs, nutrition classes, support groups, etc., while providers in more urban areas felt confident in their ability to meet all of their patients' needs. Primary care providers and often pharmacists have limited interaction and communication with specialists involved in diabetes and cardiovascular disease care. The challenge, they noted, is largely due to geographic proximity and high demand for those specialist providers given their high patient load and limited number serving within the state.

# *Figure 4.* Provider Goals for Next 5 years (white boxes) Compared with Patient Needs (solid color boxes) Relevant to the Identified Goal



**Payer/Others:** The third group consisted of representatives of one health plan, which has approximately 180,000 covered members throughout South Dakota and Iowa. Also in this group were representatives of an organization through the South Dakota Department of Health that provides centralized repository for automatic upload of electronic health record information from 63 hospitals and 375 primary care clinics in the region that providers within the network can access to facilitate patient care provision. This was a smaller group (n=8) than the others but the data collected was no less robust. Participants in this group represented different roles within their respective organization, which allowed for well-rounded discussions.

The health plan involved in the project does not currently provide MTM services or reimbursement to its providers to offer this care to covered patients, though it is planned to be implemented in the near future. The health plan had a wish list of items they would like before they can get this in place:

- Webinars to educate on MTM reimbursement
- Educational tools for providers and health plan employees on MTM
- Educational efforts for providers to understand the role of pharmacists and what services they can provide for their patients
- Policies on MTM reimbursement

Themes from the discussions in this group were <u>education</u>, <u>communication</u>, and <u>holistic wellness</u>. Almost every participant mentioned the need for education on various topics, including MTM, population health, coding/billing practices, roles of members of the healthcare team, and disease management. Communication was mentioned multiple times as causing challenges and barriers for patients, payers, and practitioners. Lapses in communication have resulted in inconsistency in how patients are treated, services that are offered to patients, and "turf wars." When asked about incorporating pharmacists more into a patient's journey and taking on a bigger role in disease management, one participant stated,

"Traditionally, this has been the role of only the physician. This isn't working. Pharmacists could take the burden off of providers, allowing them more time to provide valuable patient visits."

In regard to holistic wellness, stakeholders in this group mentioned numerous times that health systems around the nation are starting to look at patients more holistically, rather than one symptom or one disease. Some even pointed out that pharmacists are in a unique position to see patients this way, stating that pharmacists often have more contact with patients than others in the healthcare team, putting them in an ideal position to positively impact patients' disease management. Insurance providers realize that having pharmacists with more of a presence in healthcare settings are needed. One representative of the health plan

group expressed, "I can know insurance policies down to the nitty gritty, but I don't know anything about medications."

Participants representing the organization managing electronic health records were not as aware of MTM services but provided needed context about the services they provide as an organization. First, they expressed the difficulty they have with some specialty providers (dietitians, CDEs, etc.) and pharmacists seeing the benefit of becoming a member of the network. Right now, they don't have pharmacists inputting data into their system, but some pharmacists utilize existing clinical data imported from other organizations for patient care provision. This organization has a sizeable membership but is continuing to grow their network through additional members, including pharmacies. Besides not being fully aware of the benefits of becoming a member, the biggest challenge to pharmacies not joining the network often lies in the upfront costs associated with accessing the database.

### Sustainability/Data Driven Decision-Making

The project team will maintain the list of stakeholders from Year One and utilize them for future opportunities with the project, such as program development and advisory board functions. Several patients requested to be informed about any reports that were published or future opportunities to participate in this and other projects. Stakeholders in the practitioner and payer/others groups expressed interest in seeing results from the other groups to assist them in their goals and meeting patient needs. The results from the landscape analysis will provide a baseline with which to move forward and build effective programs.

### Health Impact

Thus far, health has not been directly impacted. Understanding the results gathered from Year One will contribute to measurable changes in all of the categories listed in the future.

## 5) Conclusions & Recommendations

### Recommendations

By including patients, practitioners, and payer/others organizations in this project, we have been able to use a wider lens to capture the landscape analysis of the management of chronic diseases in SD. Each of these groups has a unique perspective on the issue at hand, and through the interviews and discussions, we have been able to get a clearer picture on what the next steps should be for the project. In the next year of the project, we will work on improving our methods and building from the valuable information we gathered in the first year.

The interviews and focus groups provided rich data and the questions the SDSU team asked supplied important health information from stakeholders. As we move into the quantitative analysis phase of this project, collecting additional demographic information would be helpful. Social determinants of health, such as age, highest degree obtained, insurance type, and race were obtained in some instances; however, it would be helpful in the future to have this readily available for all participants because they are risk factors for chronic conditions and may impact overall health outcomes (Edlin, 2019; Sherman, 2019).

Due to the short timeline of the first year and efforts to meet the deliverables, we did not actively recruit American Indians. While the three stakeholder groups had a good distribution among participants, there was no presence of this important group within South Dakota. In SD, the percentage of American Indians diagnosed with diabetes is twice that of the general adult population (16% compared to 8%). In 2013, a study found that American Indian adults in SD reported significantly higher body mass index (BMI) than white adults; thus, due to the relationship between obesity and chronic conditions, American Indians in SD could be at a higher risk for cardiovascular disease and diabetes (Moon, Roh, & Lee, 2015). Therefore, it will be important to work on actively recruiting American Indian patients, practitioners, and payers for interviews and focus group sessions. This will be completed by working with two Tribal Nations in South Dakota, one in the central part of the state and one in the eastern part. Additionally, to recruit participants from the Indian Health Services (I.H.S.) in the respective communities, the SDSU team must also obtain approval from the Great Plains Area I.H.S. IRB.

Many in the PG reported not knowing about some of the services that pharmacies offered, with some even stating that they do not trust their doctors to tell them everything there is to know about a medication they prescribe. One patient even stated, "The thing is... you see the pharmacist way more than a doc," pointing out an incredible fact. Pharmacists are more accessible than physicians and patients

understand this, but do not capitalize on pharmacist services. It is estimated that 64% of SD residents live within a 15-minute drive to a pharmacy, and 81% are within a 30-minute drive (Sehr, Miller, Pugsley et al., n.d.). With more education and targeted efforts, pharmacists can become a consistent resource for patients, especially those in rural South Dakota. SDSU proposes the following strategic steps to develop, adapt, and implement education initiatives, such as an awareness campaign about MTM:

- 1. Use Year One analysis to develop resources targeting patients;
- 2. Disseminate these patient resources statewide;
- 3. Disseminate tailored resources to specific communities within the state; and
- 4. Test the effectiveness by administering pre- and post- surveys to patients

While 75% of pharmacists reported they offered MTM services (Table 2), it is important to note that in many instances we specifically did not ask if they performed all the core elements of MTM for each patient presenting with a chronic condition. Several pharmacists reported performing elements of pharmacists' patient care process (PPCP) irrespective of setting, but a large number did not specifically complete all aspects of the process. For example, the pharmacist would collect information from a patient but may not follow-up or implement a plan of action. By law, pharmacists are required to offer counseling to any patient that picks up a prescription. Many pharmacists assume this to mean they are offering MTM services. This might explain why a large number of pharmacists reported they were offering these services but when prompted about creating a Medication Action Plan or a Personal Medication Record, which are two of the core elements of MTM programs, many pharmacists stated they seldom offer these services to patients, unless it was specifically requested. In Year Two, it would be beneficial to explore this further by developing a survey to collect this data. Pharmacists often mentioned a basic understanding of MTM but had not had adequate training in a professional capacity. Another discrepancy that could be addressed with additional exploration is the difference between offering MTM services and actively performing these services for every patient.

Recommendations from the final stakeholder group, the payer/others, focused mostly on educational needs. A resounding message about confusion around MTM services and how those services would be reimbursed brings forth the necessity of targeted education for members of their health plans, providers, and other employees of the health system. One limitation with this group came again from the SDSU team's effort to stay on track with the deliverables. While we collected indepth and fruitful data from those representing this health plan, we realize that more perspectives are needed in the future.

Payers also expressed the need for more tools and resources within clinics and pharmacies to reduce confusion about what services or medications are covered under their plans. There has been success in other states with collaborative practice agreements (CPAs) between physicians and pharmacists, which allow those pharmacists to perform duties that are typically associated with a physician, such as ordering lab tests, selecting medication regimens through delegated prescriptive authority, and adjusting those regimens (Edlin, 2019). While South Dakota has similar protocols in place currently, we hope to bring increased focus on consistency with offering these services, especially in rural environments. While there was awareness of CPAs, several pharmacists did not report having one in place. The lack of awareness on how CPAs work and how to set them up was mentioned as a major barrier to implementation at their practice site's rate limiting step. A key recommendation for this group was education within and across practitioner groups statewide. As we develop educational initiatives to address these knowledge gaps and expand on the existing knowledge base among practitioners about pharmacy-based services, including MTM, we plan to pay close attention to covering topics such as CPAs. Along with these types of examples, other resources that payers from the project suggested including were guides or examples of educational materials that work effectively for members with diseases such as diabetes.

### Conclusions

Diabetes and cardiovascular disease are highly prevalent throughout the country (ADA, n.d.). This is also true in SD, and based on data obtained from this project, healthcare providers and payers report high prevalence of both; however, the difference between national response to these diseases and the SD response is compounded due to challenges relating to the rurality of the state and its impact on patients' access to needed services. Patients talked about difficulty in finding specialists to treat their disease, such as endocrinologists and cardiologists, and rising costs of managing their disease, which is a valid concern as costs of managing chronic diseases in SD are rising (Sehr, Miller, Pugsley et al., n.d.). The first year of this project revealed the committed work that our healthcare system is doing for patients; patients saw and appreciated the extra efforts that many of the state's healthcare professionals put forth. Patients expressed regret at not taking seriously their healthcare team's warnings about their disease and some of the patients that took part in the project have been able to build a relationship with at least one member of their healthcare team. Patients talked about long wait times, not enough time with their primary care providers, and high healthcare costs. Sometimes these factors all worked together to result in extreme health inequities for patients dealing with chronic conditions that require close supervision to prevent further complications.

Patients stated that they have noticed the extra effort and care that they see from pharmacists and, on occasion, have come to trust them more than their primary care provider (PCP). Pharmacists have the unique opportunity to interact with patients on a different level than others on the healthcare team on a frequent basis, allowing them to fill the gaps in care that those with chronic conditions can face. These points are further reinforced due to the benefit of access that pharmacies provide. Patients and payers are also beginning to see the benefit of having pharmacists becoming more intertwined in the healthcare journey. A holistic approach to patient care and disease management is gaining traction among healthcare providers of all disciplines, further justifying the need to incorporate pharmacists as team members to manage diseases and improve health outcomes (Sherman, 2019) (Moon, Roh, & Lee, 2015).

Overall, there continues to be lack of awareness of MTM services and the enhanced role that pharmacists could play within the healthcare system. This unawareness was present among participants in all three groups of the project; once it was explained more, there was a general consensus that MTM services would be a welcomed addition to chronic disease management. Pharmacists have the potential to help improve access to care in SD by providing medication-related services, including through drug therapy protocols and/or collaborative practice agreements with physician(s), where the pharmacists are delegated prescriptive authority as outlined in the agreement in order to manage a specific aspect of care on behalf of the physician. Given their expertise in medication knowledge and appropriate use, pharmacists can improve patient access to healthcare through provision of clinical services such as immunization administration, MTM services, disease state management, diabetes education, and point-of-care testing.

To the best of our knowledge, there has never been a report that looked at these three stakeholder groups across the state, especially in the context of MTM services to treat chronic conditions. This landscape analysis provides a strong foundation for targeted program development and practice transformation across the state in the upcoming years.

**Acknowledgements:** We would like to acknowledge and thank the following individuals/organizations for their assistance in Year One of this project

- Ms. Bisola Olomola, MPH, Research Associate
- Staff at the South Dakota Department of Health Office of Chronic Disease Prevention, especially Rachel Sehr, BSN, RN, Heart Disease and Stroke Prevention Coordinator and Kayla Magee, RN, Diabetes Program Coordinator
- Ryan Loo, PhD from Spectrum Health Policy Research (SHPR)
- Staff at the College of Pharmacy and Allied Health Professions at South Dakota State University
- Sharon Knoll, Director of Account Services from Media One

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# Appendix B: Classified Ads in Newspaper



If you or someone you know has any of the above conditions or is taking medications for the above conditions and would like to participate in a research study



IRB-1901020-EXM



# Appendix C: Facebook Pop-ups

Appendix D: Poster Stands



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# Appendix E: Codebook

# CODEBOOK

Theme/Code	Description/SampleText
Access to Care	<ul> <li>(cost, geographic constraints)</li> <li>"my second challenge is for me now seeing the endocrinologist here in Sioux Falls, so I have a financial expense. Um, I tried switching to one in Rapid City, but they weren't accepting new patients so, I didn't have any choice but to keep coming back here."</li> <li>(Income)</li> <li>"I'm on disability so I live on a fixed income"</li> </ul>
Behavior Modification	Dietary/Nutrition "let's start diet first because when you are so sedentary it's like my bones-my knees were getting sore, I was gaining weight so he just said for 2 weeks let's just take dairy out of your diet and see what that does. We just made small little changes, trying things to see how we feel. If it's helping, if any symptoms or not, but and then we did gluten for 2 weeks and then, um, we did meat for 2 weeks and then was like I could definitely tell I was gluten sensitive."
	"And, you know, it's usually the community garden has it all plowed and stuff and I usually save my seeds from the year before, so I don't have that expense and it gets me outside and it gets me moving and, you know, I love eating fresh food. Other than that, I am a coupon cutter like crazy" "now, I do a lot more walking because of it, especially after I eat"
Chronic Conditions	"born with a congenital heart defect and I have pulmonary hypertension (patient refers to this as PH throughout the interview) called CTEPH (Chronic Thromboembolic Pulmonary Hypertension) from embolisms in my lungs that clogged up my pulmonary arteries"
Coping with Diagnosis	"Didn't know what to expect I actually was really honestly for the first few days just in shock"

Theme/Code	Description/SampleText
Current Medications	Any reference to meds identified by interviewee
Diabetes Education	"The doctor never sends me to the nutrition or the nutritionist or for any repeat diabetes education classes"
Discovery of Diabetes	"Actually the morning that I got up after I had that hole (the PFO) closure, a fellow doctor came in and um, I had just woken up and he said the surgery went well, by the way, you have diabetes"
Disease Challenges	"one of the challenges is, was I just had spine surgery so I was on pain medication, including a fentanyl patch, which the whole world just goes crazy over right now"
Disease Physical Impact	"One thing I've noticed is that I think I'm pretty in tune with my body, so when I start to feel a little, I know this sounds weird, but like internal shaky, I know I need to eat something"
Disease Progression	"Uh that was back in 2004 and subsequently after 6 months she took me off my blood thinners and 5 months later I ended up having a stroke"
Disease Self-Management	"And my third one, I would say is just being mindful of keeping my meter in my car or my purse with me and stuff, you know"
Direct to Consumer Advertising (DTCA) Influence	"Uh, no actually and speaking of like diabetes, I laugh every time I see that like oh, because these people are like walking around doing stuff and it's like, when I go to the endocrinology clinic, those are like, the most pathetic people, like they are just not what are being portrayed on TV, youknow"
MTM/Pharmaceutical Care/Counseling	"I just kinda asked the pharmacist what time of the day was best to take it. He actually gave me more information and printed it out from his computer"
Access (to care services, medication, etc.)	"before when medications weren't coming in on time or, oh, our truck didn't come in and we didn't get the order in—I used to work at a pharmacy part-time, so I know there's challenges getting it,"

Theme/Code	Description/SampleText
	"I've been handed a prescription so many times and I go to fill it and it's not covered."
Medication Adherence	"Just goes off and I just stop whatever I'm doing-I just pull over and take my meds." (take meds) "Religiously because if I don't do my part it's not going to work. I have a little alarm on my phone that just"
Innovative Treatments	"We got this this drug trial, we got me into a drug trial about 6 weeks later and here I am, no oxygen."
Uncommon or Life Threatening Symptoms	"And they—my pulmonologist, finally said 'I'm admitting you to the hospital until we figure this out.' And they said most people, you know, in their childhood or as babies they catch that hole, but it just"
Patient Empowerment	"Sought it out myself" "Yea, because its changing and so many things are changing that, you know, its like I kinda want to keep up on it and see what's new and, I mean, even the meters change so much" "I literally went onto some search engine and said, you know, 'who do I need to see here?'"
Patient/Provider Relationship- Communication	"And it's encouraging, like, you've got somebody there as a sounding board for things that go well and don't go well and so"
Provider Referral	<ul> <li>"yes I saw just my regular doctor that I saw all the time and she suggested we send me to an endocrinologist friend of hers at the University of Colorado so…"</li> <li>"Yep, you go to the national WWPHAssociation.com and he's the only one listed for the state…"</li> <li>"I had my PFO hole closed and the initial study down at National Jewish and then they sent me to the University of Colorado to a heart specialist there…"</li> </ul>
Gaps in Treatment or Services/Unmet Needs	"Now I can't get back in to see my doctor for 3 or 3 and a half weeks because they're booked out and so I just have a lapse of nothing and then you go back and they're like 'well this has really gotten a lot worse'"

Theme/Code	Description/SampleText
	"where they were going to make some really grave mistakes with me. You know, one time when I was in the hospital and they hooked up this huge IV and I said "you cannot overload me on fluid because I will go into heart failure"
	"Honestly, I think there's so many people that are zoned in to one specialty that they are kind of uneducated to the zebras in the community. Um, they like-ongoing education for, you know, I think the way people are progressing in the world, diseases are progressing and I think ongoing education needs to serve those needs"
	"Don't know what that looks like, but like I said when I register with some, I say I need a copy of today's visit and every visit-going to all of these doctors so that they all can see what is happening"
	"there's so many things that need more than 10 minutes of attention and it needs to be more well rounded. It cannot just be about them walking in, checking the blood pressure, weight, and doing a med list"
	"I've been handed a prescription so many times and I go to fill it and it's not covered."

Appendix F: SDSU IRB Approval



- Date: January 29, 2019
- Investigator: Sharrel Pinto
- Project Title: Improving the Health of South Dakotans through Prevention and Management of Diabetes, Heart Disease and Stroke-Landscape Analysis

Determination: Exempt, Category 2

Approval #: IRB-1901020-EXM

The project referenced above is exempt from further review by the Institutional Review Board of South Dakota State University. Exemption is claimed on number(s) 46.104 (d) (2) of the criteria for exemption outlined in 45 CFR 46, section 104.

Note: If the project is changed, it should be re-submitted to the IRB for a determination of whether it still satisfies exemption criteria.

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Dianne Nagy Research Integrity and Compliance Officer



Date:	March 19, 2019
Investigators:	Sharrel Pinto, Chamika Hawkins-Taylor, and Alex Middendorf
Project Title:	Improving the Health of South Dakotans through Prevention and Management of Diabetes, Heart Disease and Stroke-Landscape Analysis
Determination:	Exempt, Category 2
Approval #:	IRB-1901020-EXM

The protocol changes requested for the project referenced above have been approved by the Institutional Review Board (IRB) for the protection of human subjects through expedited review. You may add the identified investigators to the research team.

The study continues to be covered by the review detailed in your original approval letter.

Unanticipated problems or adverse events must be promptly reported to the IRB. Please notify the IRB when your study concludes.

Sincerely,

Dianne Mago

Dianne Nagy Research Integrity and Compliance Officer