"Organization or Clinic Name"

Delegated Functions	Minimum Training and Experience
Participate directly in the assessment and management of the adult patients with type 2 diabetes, hypertension, hyperlipidemia, and/or polypharmacy who are under the collaborative care of the clinical pharmacists and the delegating physicians.	Authority to assist in medical treatment and medications and to order diagnostic tests is derived from the delegation of that authority by the licensed physicians, who shall supervise the performance of those delegated functions, in accordance with the Michigan Public Health Code (1978 P.A. 368), including, but not limited to Section 16109(2); 16215; 17708(2).
 Care provided includes: Refer to and update as necessary the health and medical history. Evaluate therapeutic regimen based on efficacy, safety, adverse effects, drug interactions, drug cost, patient preferences, and "Organization Name" Clinical Care Guidelines. Collaborate in the medication management (initiate, modify, or discontinue) for the treatment of type 2 diabetes, hypertension, hyperlipidemia, and/or polypharmacy based on written protocols approved by physicians under the collaborative practice agreement. Perform blood pressure measurement and diabetes foot screening including monofilament test. Provide self-management education. Set and record self-management of type 2 diabetes, hypertension, and hyperlipidemia including A1c, urinary microalbumin, CHD profile, alanine aminotransferase (ALT), basic metabolic profile/comp metabolic panel. Facilitate referrals on behalf of physicians to type 2 diabetes. Facilitate referrals on behalf of physicians to type 2 diabetes. Facilitate referrals on behalf of physicians to type 2 diabetes education classes, diabetes eye exam, nutrition counseling as needed. Document services provided in the electronic medical record 	 Qualifications: Pharmacists practicing at "organization or practice name" under a Collaborative Drug Therapy Management Agreement (CDTM) must satisfy all of the qualifications listed below: Licensed by the State of Michigan. Completion of a Doctorate of Pharmacy (PharmD) degree. Completion of a Pharmacy Practice Residency accredited by the American Society of Health System Pharmacists (ASHP) or three (3) years of relevant clinical experience in the specific practice area covered by the CDTM Agreement or Certification from the Board of Pharmacy Specialties. Completion of on-site training in direct patient care by shadowing delegating physicians for a minimum of 4 full clinic days upon hire. Competency Assessment: Formal evaluation of each pharmacist functioning under a CDTM Agreement must occur <u>"enter timeframe"</u>, and each evaluation must review a minimum of x cases evenly distributed across each condition/diagnosis managed, or all cases if less than xx. Supervising physicians must be directly involved in the review of the pharmacist's practice. All evaluations must be forwarded to <u>""</u> for review.
Communication with physicians:	

The p with t any c physi	oharmacist will be responsible for consulting the patient's physician in a timely fashion if of the following incidents occur. The ician will evaluate the patient as needed: Pharmacotherapy efforts are failing despite following treatment outlined in written protocols. Major side effects become apparent. Any acute medical problem is observed, either new or an exacerbation.
• Ther	oharmacist should routinely communicate
with t	he patient's physician.
\checkmark	Physicians will co-sign all prescriptions.
\succ	Physicians will co-sign all lab orders.
\blacktriangleright	Lab results must be sent to the physician's inbox.
	Physician is responsible for all abnormal results.
>	Notes regarding initiation of new medications, which a pharmacist may make only if consistent with the appropriate written protocol and the CDTM Agreement, must be forwarded to the physician's inbox as agreed upon in advance.
À	Notes with dosing changes within written protocols may be forwarded to the physician's inbox at physician discretion.
>	Real-time discussions of the patient's needs or issues outside of the written protocols as needed.

The licensed physicians signed below are working in collaboration with <>, Pharm.D. and agree to delegate and supervise the medical functions defined in the Scope of Services document.

Authority to prescribe medical treatment and medications and to order diagnostic tests is derived from the delegation of that authority by the licensed physicians signed below who shall supervise the performance of those delegated functions, in accordance with the Michigan Public Health Code (1978 P.A. 368), including, but not limited to Section 16109(2);16215; 17708(2).

<mark>< ></mark>, MD

Date

Add additional lines for physician signatures or use separate document for each physician.



^a PCP will be notified via notes in "EMR";PCP will co-sign prescriptions
 ^b Consult with PCP as needed
 ^c In patients with CAD and/or CHF, consider beta blocker

Table 1: First Line Antihypertensive Medications

Drug Class and Generic Name	Brand Name	Usual Dosage Regimens
Thiazide Diuretics		
hydrochlorothiazide		12.5mg.daily 25mg daily 50 mg daily
chlorthalidone		25 mg daily
indapamide		1.25 mg daily 2.5 mg daily
ACE Inhibitors		
benazepril	Lotensin	5 mg daily 10 mg daily 20 mg daily 40 mg daily
quinapril	Accupril	10 mg daily 20 mg daily 40 mg daily
lisinopril	Prinivil/Zestril	5 mg daily 10 mg daily 20 mg daily 40 mg daily
enalapril	Vasotec	2.5 mg daily 5 mg daily 10 mg daily 10 mg BID
fosinopril	Monopril	10 mg daily 20 mg daily 40 mg daily
trandolapril	Mavik	1 mg daily 2 mg daily 4 mg daily
moexipril	Univasc	7.5 mg daily 15 mg daily
ramipril	Altace	2.5 mg daily 5 mg daily 10 mg daily
perindopril	Aceon	4 mg daily 8 mg daily
Angiotensin Receptor	r Blockers	
telmisartan	Micardis	40 mg daily 80 mg daily
olmesartan	Benicar	20 mg daily 40 mg daily
valsartan	Diovan	80 mg daily 160 mg daily 320 mg daily
irbesartan	Avapro	150 mg daily 300 mg daily
candesartan	Atacand	8 mg daily 16 mg daily 32 mg daily
eprosartan	Teveten	400 mg daily 600 mg daily
losartan	Cozaar	50 mg daily 100 mg daily 50 mg BID
Dihydropyridine Cal	cium Channel Blocker	S
amlodipine	Norvasc	5 mg daily 10 mg daily
felodipine	Plendil	5 mg daily 10 mg daily
nifedipine CC	Adalat CC	30 mg daily 60 mg daily 90 mg daily
	Procardia XL	
nisoldipine	Sular	20 mg daily 30 mg daily 40 mg daily
isradipine	Dynacirc CR	2.5 mg BID 5 mg BID

Drug Class and Generic Name	Brand Name	Usual Dosage Regimens
Aldosterone Antagoni	sts	
spironolactone	Aldactone	25 mg daily 50 mg daily
eplerenone	Inspra	50 mg daily 50 mg BID
Potassium Sparing/Th	iazide Combination Diu	retics
amiloride /HCTZ		5 mg/50 mg daily
triamterene/HCTZ		37.5 mg/25 mg daily
spironolactone/HCTZ		25 mg/25 mg daily
Beta Blockers		
atenolol	Tenormin	25 mg daily 50 mg daily 100 mg daily
metoprolol tartrate	Lopressor	50 mg BID 100 mg BID
propranolol	Inderal LA	40 mg BID 80 mg BID
propranolol	Inderal XL	60 mg daily 80 mg daily 120 mg daily
labetalol	Trandate/Normodyne	100 mg BID 200 mg BID 300 mg BID
nadolol	Corgard	40 mg daily 80 mg daily 160 mg daily
metoprolol succinate	Toprol XL	100 mg daily 200 mg daily
nebivolol	Bystolic	2.5 mg daily 10-20 mg daily 40 mg daily
carvedilol	Coreg	3.125 BID 12.5-25 mg BID 25 BID
	Coreg CR	10mg daily 20 mg daily 40 mg daily 80 mg daily
Non-Dihydropyridine	Calcium Channel Block	iers
verapamil SR	Calan SR	240 mg daily
diltiazem	Cardizem	30 mg QID 60 mg TID 60 mg QID 90 mg TID
diltiazem CD	Cardizem CD	120 mg daily 180 mg d 240 mg d 300 mg daily
Central Acting Agent	s	
clonidine	Catapres	0.1 mg BID 0.2 mg BID 0.3 mg BID
clonidine patch	Catapres-TTS	0.1 mg/24 hr 0.2 mg/24 hr 0.3 mg/24 hr
methyldopa		250 mg TID 500 mg TID 1000 mg TID
Vasodilators		
isosorbide dinitrate		10 mg TID 20 mg TID 40 mg TID
hydralazine		25 mg TID 50 mg TID 100 mg TID
Alpha Blockers		
doxazosin	Cardura	1mg daily 2mg daily 4mg daily
terazosin	Hytrin	1mg daily 2mg daily 5mg daily
prazosin	Minipress	1mg BID 2mg BID 5mg BID

Table 2: Alternative Antihypertensive Medications

Table 2: Alternative Antihypertensive Medications, continued

Renin Inhibitors			
aliskiren	Tekturna	150 mg daily	300mg daily
Other Diuretics			
furosemide	Lasix	20 mg BID	40 mg BID
torsemide	Demadex	5 mg daily	10 mg daily

Monitoring Parameters:

Diuretics

- Check creatinine/K+ as part of Basic or Comp Profile within 2 4 weeks of starting treatment or increasing dose
- Use cautiously in patients with gout (can increase uric acid concentrations). Notify provider if patient develops symptoms of gout.

ACE-I/ARB:

- Check creatinine/K+ as part of Basic or Comp Profile within 2 4 weeks of starting treatment or increasing dose
- May cause hyperkalemia; monitor closely in patients at high risk (K>4.5 mEq/L, renal insufficiency, on other drugs that can cause hyperkalemia such as spironolactone, drospirenone, potassium supplements or diuretic combinations)

Beta-Blockers:

• Monitor HR (can cause bradycardia, especially in patients also taking verapamil, diltiazem, or digoxin). Notify provider if patient's HR drops to < 50 or symptomatic.

Calcium-channel Blockers (DHP CCB):

• Monitor peripheral edema. Notify provider if patient develops peripheral edema.

Therapeutic Management of Type 2 Diabetes



¹ PCP will be notified via notes in "EMR"; PCP will co-sign prescriptions

² Refer to Insulin Initiation and Insulin Adjustment protocols

³ Patient specific factors may include hypoglycemia risk, weight, side effects, and drug costs

Generic (Brand Name)	Strength (mg)	Initial Dose (mg)	Max Daily Dose (mg)	Usual Daily Dose (mg)	
Biguanide Metformin (Glucophage)	500, 850, 1000	500 or 850 once daily	2550	1500-2000 divided (BID)	
Metformin extended release (Glucophage XR/Fortamet)	500, 750	500 daily with evening meal	2000, 2500mg for Fortamet	1500-2000 daily or divided	
DPP-4 inhibitors					
Sitagliptin(J anuvia)	25, 50, 100	50-100 daily	100	100 daily	
Saxagliptin (Onglyza)	2.5, 5	2.5-5 daily	5	2.5-5 daily	
Linagliptin (Trajenta)	5	5 daily	5	5 daily	
Alogliptin (Nesina)	6.25, 12.5, 25	25 daily	25	25 daily	
GLP-1 agonists					
Liraglutide (Victoza)	Multidose pen	0.6 mg once daily	1.8 mg once daily	1.8 mg once daily	
Albiglutide (Tanzeum)	30mg, 50mg	30mg once weekly	50mg once weekly	30-50mg once weekly	
Dulaglutide (Trulicity)	0.75mg, 1.5mg	0.75mg once weekly	1.5mg once weekly	0.75mg-1.5mg once weekly	
Exenatide (Byetta)	5mcg, 10mcg	5 mcg twice daily - 10 mcg BID	10mcg	10mcg BID	
Exenatide Extended-Release (Bydureon)	2mg	2mg once weekly	2mg	2mg once weekly	
Lixisenatide ¹ (Adlyxin)	10mcg, 20mcg	10mcg once daily	20mcg once daily	20mcg once daily	
Sulfonylureas (Second Generation)					
Glimepiride (Amaryl)	1, 2, 4	1-2 daily	8	4 daily	
Glipizide (Glucotrol)	5, 10	2.5, 5 daily	40	10 - 20 divided (BID)	
Glipizide ER (Glucotrol XL)	2.5, 5, 10	5 daily	20	5 - 20 daily or divided (BID)	
Glyburide ² (Diabeta, Micronase)	1.25, 2.5, 5	2.5-5 daily	20	5 - 20 daily or divided (BID)	

Footnotes:

- 1. Expected to be available late 2016
- 2. Use glyburide with caution (higher risk of prolonged hypoglycemia in older adults and those with renal impairment)

Table 1

Table 2

Generic (Brand Name)	Strength (mg)	Initial Dose (mg)	Max Daily Dose (mg)	Usual Daily Dose (mg)
Thiazolidinedione Pioglitazone (Actos)	15, 30, 45	15-30 daily	45	15 - 45 daily
Alpha-glucosidase inhibitor Acarbose (Precose)	25, 50, 100	25 daily with meal	300	50 - 100 TID before meals
Miglitol (Glyset)	25, 50, 100	25 daily with meal	300	25 - 100 TID
Non-sulfonylurea insulin secretagogues				
Repaglinide (Prandin)	0.5, 1.2	0.5 with meals	16	0.5 - 4 AC to QID
Nateglinide (Starlix)	60, 120	60–120 with meal	360	60 - 120 AC
Sodium-glucose cotransporter 2 (SGLT-2) inhibitors				
Empagliflozin(J ardiance)	10, 25	10 daily	25	10-25 daily
Canagliflozin (Invokana)	100, 300	100 daily	300	300 daily
Dapagliflozin (Farxiga)	5, 10	5 daily	10	5 in AM

Table 3: Combination agents

Generic (Brand Name)	Strength (mg)	Initial Dose (mg)	Max Daily Dose (mg)	Usual Daily Dose (mg)
Glipizide/metformin (Metaglip)	2.5/250, 2.5/500, 5/500	2.5/250 daily- 2.5/500 BID or 2.5/500-5/500 BID	10/2000 or 20/2000	Titrate to effective dose (not over max)
Glyburide/metformin(Glucovance)	1.25/250, 2.5/500, 5/500	1.25/250 daily- BID or 2.5/500- 5/500 BID	10/2000 or 20/2000	2.5/500 – 10/1000 daily-BID
Repaglinide/metformin (PrandiMet)	1/500, 2/500	1/500 BID within 15 min prior to meal	10/2500	Titrate to effective dose (not over max)
Pioglitazone/metformin (Actoplus Met)	15/500, 15/850	15/500-15/850 daily-BID	45/2550	Titrate to effective dose (not over max)
Pioglitazone/metformin ER (Actoplus Met XR)	15/1000, 30/1000	15/1000- 30/1000 daily	45/2000	Titrate to effective dose (not over max)
Sitagliptin/metformin (Janumet)	50/500, 50/1000	50/500 BID or 50/1000 BID	100/2000	Titrate to effective dose (not over max)

This form was developed by MPTCQ

Sitagliptin/metformin ER (Janumet XR)	50/500, 50/1000, 100/1000	50/500 BID or 50/1000 BID or 100/1000 daily	100/2000	Titrate to effective dose (not over max)
Linagliptin/metformin (Jentadueto)	2.5/500, 2.5/850, 2.5/1000	2.5/500 BID or 2.5/850 BID or 2.5/1000 BID	5/2000	2.5-5/2000 mg per day
Linagliptin/metformin ER (Jentadueto XR)	2.5/1000, 5/1000	2.5/1000 daily or 5/1000 daily	5/1000	2.5-5/1000 mg per day
Saxagliptin/metforminER (Kombiglyze XR)	2.5/1000, 5/500, 5/1000	2.5/1000 daily 5/500 daily or 5/1000 daily	5/2000	2.5-5/2000 mg per day
Alogliptin/metformin (Kazano)	12.5/500, 12.5/1000	12.5/500 BID ^e or 12.5/1000 BID	25/2000	25/2000 mg per day
Canagliflozin/metformin (Invokamet)	50/500, 150/500, 50/1000, 150/1000	50/500 BID ^e or 150/500 BID or 50/1000 BID or 150/1000 BID	300/2000	100-300/2000 mg per day
Dapagliflozin/metformin ER (Xigduo XR)	5/500, 10/500, 5/1000, 10/1000	5/500 daily-BID ^e or 5/1000 daily- BID ^f or 10/500 daily or 10/1000mg daily	10/2000	5-10/2000 mg per day
Empagliflozin/metformin (Synjardy)	5/500, 5/1000, 12.5/500, 12.5/1000	5/500 BID or 5/1000 BID or 12.5/500 BID or 12.5/1000 BID	25/2000	10-25/2000 mg per day

Insulin Initiation Protocol

- 1) Start with NPH, detemir, or glargine
- 2) The choice may vary depending on concerns regarding endogenous insulin secretion, need for mealtime insulin coverage, cost and convenience.
- 3) All patients started on insulin should demonstrate use of a glucometer and be educated on recognition and treatment of hypoglycemia.

NPH, detemir, or glargine insulin

- a. Continue metformin +/- sulfonylurea depending on preprandial glucose.
- b. Add 10-20 units of NPH, detemir, or glargine insulin daily
- c. Then increase insulin by 10% or 2-4 units every 3 days until attaining the goal of a fasting blood glucose <130 mg/dL without hypoglycemia.
- d. Once fasting glucose is at goal, check post-prandial glucoses; if > 180 mg/dL consider adding either rapid or regular insulin before meals.

NPH or detemir insulin (BID)

- a. Continue metformin, discontinue sulfonylurea.
- b. Add 5-10 units of NPH or detemir insulin at breakfast and dinner (or bedtime).
- c. Then increase insulin by 10% or at least 2 units every 3 days until attaining the goal of a fasting blood glucose and pre-dinner glucose < 130 mg/dL without hypoglycemia.
- d. Once fasting glucose is at goal, check post-prandial glucoses; if > 180 mg/dL consider adding either rapid or regular insulin before meals.

Premixed insulin (intermediate & short-acting or rapid-acting mixtures)

- a. Continue metformin, discontinue sulfonylurea.
- b. Add 10 units of pre-mixed insulin at breakfast and dinner.

c. Then increase pre-breakfast and/or pre-dinner insulin by 10% or at least 2 units every 3 days until attaining the goal of a fasting and pre-meal glucose level < 130 mg/dL without hypoglycemia.

Table 4: Available insulin preparations

Туре	Onset	Peak	Duration
Rapid Acting			
Lispro (Humalog) (100 u/mL and 200 u/mL)	15-20 minutes	0.5-2.5 hours	3-5 hours
Aspart (Novolog)			
Glulisline (Apidra)			
Regular			
Humulin R	30-60 minutes	2-3hours	3-6 hours
Novolin R			
Intermediate Acting			
Insulin NPH (Humulin N)	2-4 hours	4-10 hours	10-16 hours
Insulin NPH (Novolin N)			
Pre-Mixed			
Insulin NPH/insulin regular (Novolin 70/30)	30-60 minutes	2-8 hours	10-18 hours
Insulin NPH/insulin regular (Humulin 70/30)			
insulin aspart- protamine/insulin aspart (Novolog Mix 70/30)	15 minutes	2-10 hours	10-18 hours
insulin lispro-protamine- insulin lispro (Humalog Mix 75/25)			
Long Acting			
Glargine (Lantus, Basaglar 100 u/mL)	1-2 hours	No peak	20-24 hours
Glargine (Toujeo 300 u/mL)	6 hours	No peak	Up to 24 hours (dose dependent)
Detemir (Levemir)	3-4 hours	6-8 hours	6-23 hours
Ultra Long Acting			

This form was developed by MPTCQ

Insulin degludec (Tresiba)	1 hour	Minimal peak at 9 hours	Up to 42 hours
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Insulin Adjustment Protocol

If overnight or before breakfast glucoses are above/below target,	adjust the supper or bedtime dose of NPH or glargine
If before lunch glucoses are above/below target,	adjust the breakfast dose of Regular or Rapid Acting Insulin
If before supper glucoses are above/below target,	adjust the breakfast dose of NPH or adjust the lunch dose of Regular or Rapid Acting Insulin
If before bedtime glucoses are above/below target,	adjust the supper dose of Regular or Rapid Acting Insulin
If fasting glucose levels are significantly higher than bedtime levels (i.e., twice as high), consider nocturnal hypoglycemia. Have the patient check glucose level around 3:00am for 2 days during the week. If the glucose levels are:	

- normal in the middle of the night,
- low in the middle of the night,

increase the NPH supper dose decrease the NPH supper dose.

Screening Tests and Follow-up

- 1. Blood pressure: refer to Therapeutic Management of HTN Protocol
- 2. Diabetes foot screening: PharmD will perform diabetes foot screening as part of annual requirement. If abnormal, PharmD will consult with PCP.
- 3. When a PharmD identifies a need, PCP will sign off on glucose meter (must be seen by a physician/NP/PA in the past 6 months), glucose test strips, lancets, and control solution.
- 4. Facilitate ordering of a referral for diabetes eye exam every 1 2 years.
- 5. Facilitate ordering of UMA/Cr. For initial screening, abnormal test will be repeated within 3-6 months, negative test will be repeated annually. Patients on ACE-I or ARB will be excluded.



¹ ASCVD definition: ACS, history of MI, stable/unstable angina, coronary or other arterial revascularization, stroke, TIA, PAD.

² Refer to Table 1 for statin dosing

³ PCP will be notified via notes in "EMR";PCP will co-sign prescriptions
 ⁴ ASCVD risk calculator is online at <u>http://tools.cardiosource.org/ASCVD-Risk-Estimator/</u>
 ⁵ If not a candidate for high-intensity statin, then moderate-intensity statin

Table 1: Statin Dosing

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy
Daily dose lowers LDL-C on average, by approximately $\geq 50\%$	Daily dose lowers LDL-C on average, by approximately 30% to <50%
Atorvastatin (40)-80mg	Atorvastatin 10 (20) mg
Rosuvastatin 20 (40) mg	Rosuvastatin (5) 10 mg
	Simvastatin 20-40 mg
	Pravastatin 40 (80) mg
	Lovastatin 40 mg
	Fluvastatin XL 80 mg
	Fluvastatin 40 mg BID
	Pitavastatin 2-4 mg

*Bolded treatments were evaluated in RCTs and demonstrated a reduction in major cardiovascular events

*Italicized treatments are approved by the FDA but not tested in RCTs

*Modified Table 5 in 2013 ACC/AHA guidelines

Monitoring Abnormal Baseline Alanine Aminotransferase (ALT)

Careful follow-up of ALT is indicated for those with known liver disease, risk factors for liver disease, or in patients who are on other potentially hepatotoxic medications. For other patients:

- If baseline ALT is normal, no further monitoring is required.
- If baseline ALT is mildly abnormal (over upper limit of normal but < 5 X upper limit of normal): reassess ALT after 6-12 weeks of statin treatment for stability. Consider monitoring annually for stability if baseline ALT is abnormal.

Abnormal baseline ALT can frequently improve with statin therapy.