1. INFORMED CONSENT Subject ID: ____ - ___ _ Page 1 of 2



- 1. Type of consent
 - Hypertension active observation
 - Alternative asthma intervention
 - Hypertension passive observation

If 'Hypertension passive observation' is selected above, stop. Submit the form without answering any remaining questions.

2. Version of consent document

The version number or version date should appear in either the header or footer of the informed consent document or on a stamp applied to that document. *Note: The informed consent form approved by your IRB may contain either a version number or a version date, but not necessarily both. If one of the items does not appear on the form, check the N/A box for that item.*

- a. Version number: _____
 Image: N/A

 b. Version date: ____/___/____ (mm/dd/yyyy)
 Image: N/A
- 3. Date informed consent signed: ___/__/__ (mm/dd/yyyy)

SCREENING ELIGIBILITY

4. Short Portable Mental Status Questionnaire (SPMSQ) score: _____

If the SPMSQ score is >2, the subject is NOT eligible.

- 5. Baseline blood pressure control (Complete only if 'Hypertension active observation' is selected for Item 1.)
 - Average systolic <130 mm Hg AND average diastolic <80 mm Hg AND subject IS currently diagnosed with diabetes OR chronic kidney disease

Blood pressure is controlled; subject is NOT eligible.

 Average systolic <140 mm Hg AND average diastolic <90 mm Hg AND subject IS NOT currently diagnosed with diabetes OR chronic kidney disease

Blood pressure is controlled; subject is NOT eligible.

 Average systolic blood pressure >200 mm Hg OR average diastolic blood pressure >115 mm Hg

Refer to the Manual of Operations for instructions on handling hypertensive urgencies; subject is NOT eligible.

O Uncontrolled

If one of the following options is selected for Item 5, enter the subject's average research blood pressure in items 5.a and 5.b:

Option 1 – 'Average systolic <130 mm Hg AND average diastolic <80 mm Hg AND subject IS currently diagnosed with diabetes OR chronic kidney disease'

Option 2 – 'Average systolic <140 mm Hg AND average diastolic <90 mm Hg AND subject IS NOT currently diagnosed with diabetes OR chronic kidney disease'

Option 3 – 'Average systolic blood pressure >200 mm Hg OR average diastolic blood pressure >115 mm Hg'

- a. Average Systolic: _____
- b. Average Diastolic: _____

(Continue to 'Item 6' on page 2.)

Source Document Completed copy must be maintained in subject's study file

1. INFORMED CONSENT Subject ID: ____- - ___ ___ Page **2** of 2



Is the subject ineligible for another reason not listed above?
 O Yes
 O No

a. If yes, specify: _____



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Version 2.2 25/Apr/2011



Complete Part A and Part B of the paper form at <u>EVERY study visit</u> (per protocol) after the baseline visit. These items (part A and B) <u>will not</u> be entered into the database. Retain a copy (of the completed paper form) in the subject's study file for monitoring.

A. Visit Date: ___/__/_ __ (mm/dd/yyyy)

Screening Questions (to be read to the subject)

- 1. "Have you had any changes in your health since your last study visit?" O Yes O No
- 2. "Have you been hospitalized or received care in the emergency department since your last study visit?"
 - O Yes O No
- B. Serious adverse event not reported by the subject
 - Serious adverse event (SAE) found documented in medical record (Study Coordinator to review medical record for time period since last study visit):
 Yes
 No
 - 2. SAE occurred at the time of the study visit:

If your answer to one or more items in Sections A and B is Yes, skip to Section C, item 9 to verify that the event is an SAE. If the outcome of the identified event matches one or more of items C.9.a. – C.9.g., the event represents a SERIOUS adverse event (SAE). **Complete all items in Section C** on the hard copy form, **ENTER THE FORM ELECTRONICALLY**, and file the hard copy form in the subject's folder.

Also complete Section C and enter the form electronically **ANY** time an event is identified that matches one or more of the outcomes listed in C.9.a. – C.9.g (e.g., another clinic staff member or the study pharmacist becomes aware of a serious adverse event outside of a scheduled study visit).

If the outcome of the identified event is C.9.h. (None of the above), select C.9.h and **STOP HERE.** FILE the hard copy form in the subject's folder. The event represents a non-serious adverse event. Do NOT complete items C.1 - C.8 on the hard copy form. Do NOT submit the form electronically.

2. SERIOUS ADVERSE EVENT Subject ID: ____ - ___ __ Page 2 of 3



Serious Adverse Event (SAE)

- 1. Date of SAE: ___/__/__ (mm/dd/yyyy)
- 2. Date site became aware of SAE: ___/__/__ (mm/dd/yyyy)
- 3. SAE descriptor:
- 4. Was the SAE an exacerbation of a pre-existing condition (i.e. existing prior to enrollment)?

O Yes O No

- 5. Was the SAE related or might it have been related to a medication on CAPTION study list of drug codes?
 - O Yes O No

a. Medication	b. Stopped because of Adverse Event?
	O Yes
Code:	O No
	O Yes
Code:	O No
	O Yes
Code:	O No
	O Yes
Code:	O No

6. Describe any details about the SAE that might help us determine whether it is drug-related.



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Version 1.1 03/Jun/2011 2. SERIOUS ADVERSE EVENT Subject ID: ____ - ___ __ Page **3** of **3**



7. Describe relevant scans/tests/laboratory data, including dates.

8. Describe other relevant history, including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction).

- 9. Outcomes that are attributed to the SAE in the medical record or reported by the subject at the study visit (check all that apply) :
 - 🗌 a. Death
 - a.1 Date: ___/__/__ (mm/dd/yyyy)
 - □ b. Life-threatening
 - □ c. Hospitalization initial or prolonged
 - □ d. Disability
 - □ e. Congenital anomaly
 - ☐ f. Required intervention to prevent permanent impairment/damage

Option 9.f should be used for an event that does not result in death, a life-threatening condition, hospitalization, disability or congenital deformity but that did jeopardize the subject and required a specific medical intervention to prevent one or more of outcomes C.9.a – C.9.e from occurring.

□ g. Important medical event as determined by the site PI or designee

Option 9.g should only be chosen when a site judges the event to represent significant hazard or harm to a research subject.

 \Box h. None of the above

If there is **any** question about whether an event should be classified as an SAE, please **contact the CCC by phone or email for a recommendation on this decision**.

Source Document Completed copy must be maintained in subject's study file CORE

Version 1.1 03/Jun/2011 3. STUDY TERMINATION Subject ID: ____ - ___ - ___ Page 1 of 1



1.	Did the subject complete all study visits with the Study Coordinator?
	a. Date of final visit:/ / / (mm/dd/yyyy)
	O No
	b. Date of early termination:/ / (mm/dd/yyyy)
	c. Date of last study visit with Study Coordinator or Pharmacist:/// (mm/dd/yyyy)
2.	If the subject terminated the study early, please indicate the reason.
	○ Subject eligibility status changed
	a. Reason:
	○ Subject chose to withdraw
	b. Reason:
	\bigcirc Subject lost to follow-up (Unable/unwilling to travel/moved from area/unable to locate)
	 Research team chose to discontinue subject
	c. Reason:
	O Subject withdrew/terminated due to Adverse Event
	d. Specify:
	O Subject death (enter death date for question 1.b)
	O Other
	e. Specify:
	O Subject's final visit was scheduled after study closure
3.	Comments:

4. BLOOD PRESSURE DEMOGRAPHIC Subject ID: _____ - ___ ___ Page 1 of 2



1. Visit Date: __/__/___ (mm/dd/yyyy)

INSTRUCTIONS (to be read to the subject):

"The first questions ask for some basic information about you."

(Research nurse is to check the box corresponding to the subject's answers.)

- 2. Birth Date: __/_ /_ __ (mm/dd/yyyy)
- 3. Gender
 - O Male
 - O Female
- 4. Race (check all that apply)
 - a. American Indian or Alaska Native
 - 🗌 b. Asian
 - C. Native Hawaiian or other Pacific Islander
 - □ d. Black or African-American
 - 🗌 e. White
 - \Box f. Declined to answer
- 5. Ethnicity
 - O Hispanic or Latino
 - O Non-Hispanic or Non-Latino Origin
 - O Declined to answer
- 6. Education (Select the highest grade completed or degree/certificate received.)
 - \bigcirc 1 5 years
- Post-high school technical /associate degree or certificate
 4-year BA or BS degree
- \bigcirc 6 8 years \bigcirc 9 – 12 years
- Master's degree
 Doctoral degree
- 7. Insurance Status (Select only the primary insurer.)
 - O Private insurance
 - O Medicare
 - O Medicaid
 - O Other insurer
 - O None/Self-pay
 - O Free care
- 8. Insurance Coverage for Prescriptions
 - O Yes
 - O No

Source Document Completed copy must be maintained in subject's study file

4. BLOOD PRESSURE DEMOGRAPHIC Subject ID: _____ - ___ ___ Page 2 of 2



- 9. Annual Household Income
 - <\$10,000
 - \$10, 000-\$24, 999
 - \$25,000- \$39,999
 - \$40,000-\$54,999
- 10. Marital Status
 - O Never married
 - O Married
 - O Living as married
 - O Divorced or separated
 - Widowed
- 11. Smoking Status
 - O Currently smokes (If 'Currently smokes' is selected, skip question 11.c)
 - Former smoker
 - O Never smoked (If 'Never smoked' is selected, skip questions 11.a 11.c)
 - a. Number of years smoked:
 - b. Number of cigarettes smoked per day:
 - c. Elapsed time since quitting
 - \bigcirc < 5 years
 - 5-14 years
 - $\bigcirc \ge 15$ years
- 12. Current Alcohol Intake
 - O None
 - \bigcirc < 1 drink per day
 - O 1-2 drinks per day
 - O 3-4 drinks per day
 - \bigcirc > 4 drinks per day
- 13. Duration of High Blood Pressure
 - O New diagnosis
 - \bigcirc < 6 months
 - 6 months 1 year
 - \bigcirc >1 3 years
 - \bigcirc >3 5 years
 - >5 10 years
 - \bigcirc >10 years



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○ \$55,000-\$79,999
 ○ \$80,000-\$99,999
 ○ >\$100,000
 ○ Refused to answer

5. BLOOD PRESSURE MEDICATION ADHERENCE Subject ID: ____ - __ __ Page 1 of 1



Vis	sit: O Baseline O 9 months O 24 months		
A.	Visit Date:/_ / (mm/dd/yyyy)		
В.	Medication Adherence		
1.	Check medical record prior to visit: Patient has at least one active prescription for a blood pressure medication. (If not, do NOT ask remaining questions.)	O Yes	O No
2.	Some people have difficulty in taking blood pressure medication as prescribed. Do you have difficulty with this?	O Yes	O No
3.	How many days in the past week did you forget to take your blood pressure medication?		days
4.	How many days in the past week did you <u>not</u> take your medication on purpose?		days
5.	How many days in the past week did you add an extra pill?		
			days
6.	In the last 6 months, did you ever take less medicine because you felt you needed less?	O Yes	O No
7.	In the last 6 months, if you felt worse when you took the medicine, did you ever stop taking it?	O Yes	O No

6. BLOOD PRESSURE PHARMACIST ENCOUNTER Subject ID: ____ - __ __ __ Page 1 of 5



Subject Name: ______ (For site use only; do not enter into database.)

- A. PHARMACIST ENCOUNTER
- 1. Encounter Date: __/_ /_ __ (mm/dd/yyyy)
- 2. Contact Type:
 - O Initial
 - Follow-up
 - O Phone Communication
- 3. Pharmacist Code: _____
- 4. Antihypertensive Medications (list ONLY blood pressure medications that are documented as current in the medical record):

a. Medication	b. Unit Strength	c. Dose	d. Frequency	e. PRN	f. Patient Report on Adherence
					O Patient taking as prescribed
					O Patient taking but at a different dose or frequency
Code:					O Patient not taking now
					O Patient taking as prescribed
					O Patient taking but at a different dose or frequency
Code:					O Patient not taking now
					O Patient taking as prescribed
					O Patient taking but at a different dose or frequency
Code:					O Patient not taking now
					O Patient taking as prescribed
					O Patient taking but at a different dose or frequency
Code:					O Patient not taking now
					O Patient taking as prescribed
					O Patient taking but at a different dose or frequency
Code:					O Patient not taking now

6. BLOOD PRESSURE PHARMACIST ENCOUNTER Subject ID: ____ - __ __ __ Page 2 of 5



5. Blood Pressure Measurements

	1. Systolic BP (mm Hg)	2. Diastolic BP (mm Hg)
a. First BP measurement		
b. Second BP measurement		
c. Third BP measurement (optional)		

- 6. Average Blood Pressure (Removed from paper and eCRF)
- 7. Goal Blood Pressure
 - a. Goal Systolic Pressure: < _____
 - b. Goal Diastolic Pressure: < _____
- 9. Recommended lifestyle change options (check all that apply):
 - \Box a. \downarrow weight
 - b. DASH plan
 - \Box c. \downarrow sodium
 - □ d. Other diet recommendation
 - \Box e. \uparrow activity
 - \Box f. \downarrow smoking
 - □ g. Other
 - g.1 Specify: _____
 - \Box h. No lifestyle changes recommended
- 10. \uparrow BP medication compliance recommended
 - O Yes
 - \bigcirc No

- 8. Is the patient's current blood pressure controlled?
 - O Yes
 - O No



6. BLOOD PRESSURE PHARMACIST ENCOUNTER Subject ID: ____ - ___ - ___ Page 3 of 5



- 11. New Plan/Recommendations

 - Continue current regimen
 Recommend change to plan (List changes to plan in Item A.12)

12. Recommended Change to Plan:

a. Medication	b. Change Type	c. Unit Strength	d. Dose	e. Frequency	f. PRN	g. Comments	h. Physician Decision
 Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 						O Accept O Reject O Modify
Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 						O Accept O Reject O Modify
 Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 						O Accept O Reject O Modify
 Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 						O Accept O Reject O Modify
 Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 						O Accept O Reject O Modify



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6. BLOOD PRESSURE PHARMACIST ENCOUNTER	
Subject ID:	
Page 4 of 5	



13. Planned Follow-up with Pharmacist (check all that apply):

🗌 a. 1 week	🗌 b. 2 weeks	🗌 c. 4 weeks	🗌 d. 6 weeks	🗌 e. 8 weeks	☐ f. 3 months
🗌 g. Other time	irame				
g.1 Specif	y:				
h. Patient dec	lined to re-schedule		🗌 i. Pharmacist	intervention complete	d

14. Final Plan (Complete only if changed from the pharmacist recommended plan):

a. Medication	b. Change Type	c. Unit Strength	d. Dose	e. Frequency	f. PRN
	O Start New Drug				
	O Discontinue Drug				
	O Increase Dose				
	O Decrease Dose				
Code:	O Regimen Change (same dose)				
	O Start New Drug				
	O Discontinue Drug				
	O Increase Dose				
	O Decrease Dose				
Code:	O Regimen Change (same dose)				
	O Start New Drug				
	O Discontinue Drug				
	O Increase Dose				
	O Decrease Dose				
Code:	O Regimen Change (same dose)				
	O Start New Drug				
	O Discontinue Drug				
	O Increase Dose				
	O Decrease Dose				
Code:	O Regimen Change (same dose)				
	O Start New Drug				
	O Discontinue Drug				
	O Increase Dose				
	O Decrease Dose				
Code:	O Regimen Change (same dose)				



B. PHARMACIST TIME DOCUMENTATION

1. Start time: _____ (use military time, e.g. 1645)

2. End time: _____ (use military time, e.g. 1645)

Please complete the following by estimating the number of minutes you spent doing each activity.
--

3. Activity	Minutes to complete activity (circle one)
a. Medical record review prior to patient visit	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
b. Consultation with other provider or family	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
c. Patient assessment/medication history	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
d. Medical record review during patient visit	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
e. Order laboratory	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
f. Order medications/write prescriptions	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
g. Medical education	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
h. Lifestyle modification education	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
i. Education on BP measurement	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
j. Recommendations to MD	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
k. Documentation in medical record	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA

Please use the following CPT codes to code medication therapy management service(s) provided during the visit by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided:

- 99605 Initial 15 minutes, *new* patient
- 99606 Initial 15 minutes, *established* patient
- 99607 Each *additional* 15 minutes (Use 99607 in conjunction with 99605, 99606; code separately in addition to code for primary service.)

CPT code for initial 15 minutes:

Baseline encounter = 99605 (new patient) Encounters after Baseline = 99606 (established patient)

4. Number of 15 minute units of CPT code 99607 (1=15 additional minutes, 2=30 additional minutes, 3=45 additional minutes, etc.):



7. DIAGNOSED CONDITIONS Subject ID: _____- _____ Page 1 of 1



Visit: O Baseline O 9 months O 24 months

- 1. Visit Date: __/_ /_ _ _ (mm/dd/yyyy)
- 2. Diagnosed conditions (check all that apply)

For the baseline study visit, select all conditions with which the subject has been diagnosed at the time of enrollment. For each subsequent study visit, select only conditions with which the patient has been newly diagnosed since the last study visit.

- a. Diabetes
- □ b. Chronic Kidney Disease
- □ c. Coronary Artery Disease
- □ d. Congestive Heart Failure
- e. Hyperlipidemia
- f. Stroke or TIA
- □ g. Peripheral Artery Disease
- □ h. Asthma or COPD
- \Box i. Depression or anxiety
- ☐ j. Arthritis/DJD/Chronic Pain
- k. Seizures/Other Neurological Disorder
- □ I. Liver Disease
- 3. Serum creatinine tests

Enter only serum creatinine tests performed since the last study visit. For the baseline study visit, enter the subject's two most recent tests occurring prior to or at enrollment.

- a. First most recent serum creatinine test
 - 1. Value: ____
 - 2. Date drawn: ___/__/__ (mm/dd/yyyy)
- b. Second most recent serum creatinine test
 - 1. Value: ____
 - 2. Date drawn: ___/__ /__ __ (mm/dd/yyyy)



8. RESEARCH BLOOD PRESSURE MEASUREMENT Subject ID: ____ - ___ ___ Page 1 of 1



Vis	it: O Baseline O 12 months	\bigcirc 6 months \bigcirc 18 months		months 4 months	
1.	Visit Date://	_ (mm/dd/yyyy)			
2.	Height:	a. O centimeters	O inches	(Complete	e at baseline study visit only.)
3.	Weight:	a. O kilograms	O pounds		
4.	Does the patient smoke?				
	a. If yes, patient's last c ○ > 20 minutes ○ ≤ 20 minutes	ago	d:		
		go, did the patient wa ressure was measure 〇 No		since his/ł	ner last cigarette before the
5.	Time of day of BP record	ling: (u	se military time, e.g	ı. 1645)	
6.	Arm used for BP measur O Right O Let		d):		
7.	Midpoint circumference of	of arm being used (cr	n):	(Complete	at baseline study visit only.)
8.	Size of cuff used: O Small (17-22 cm) O Medium (22-32 cm				
9.	Seated pulse (beats per mi	nute):			
		a.	. Systolic BP (mm H	Hg)	b. Diastolic BP (mm Hg)

	a. Systolic BP (mm Hg)	b. Diastolic BP (mm Hg)
10. First sitting BP measurement		
11. Second sitting BP measurement		
12. Third sitting BP measurement		
13. Fourth sitting BP measurement (take ONLY if 2 nd & 3 rd BPs for systolic or diastolic differ by > 4 mm Hg)		

14. Average Systolic Pressure (add the 2 closest measurements from 11a, 12a and 13a and divide by 2): _____

15. Average Diastolic Pressure (add the 2 closest measurements from 11a, 12a and 13a and divide by 2): _____ ___

Rule for average pressures (items 14 and 15): If a 4th measurement is taken, and the 3 values (either systolic or diastolic) are equidistant apart, choose the HIGHER two values. For example, if systolic pressures = 148, 136, and 142, the average would be $(142 + 148) \div 2 = 145$.

9. ANTIHYPERTENSIVE MEDICATIONS	
Subject ID:	
Page 1 of 2	



Study Visit: O Baseline O 12 months \bigcirc 6 months \bigcirc 18 months

○ 9 months○ 24 months

A. <u>Antihypertensive</u> Medications Currently Prescribed at the Time of the Study Visit (to be completed at each study visit)

<u>INSTRUCTIONS (to be read to the subject)</u>: "I have a list of the blood pressure medications that we think you are taking. Please tell me how much of each medication you are taking or if you are not taking the medication."

1. Date of Study Visit: __/_ /_ __ (mm/dd/yyyy)

2. Medications:

a. Medication	b. Unit Strength	c. Dose	d. Frequency	e. PRN	f. Patient Report on Adherence
					O Patient taking as prescribed
 Code:					O Patient taking but at a different dose or frequency
					O Patient not taking now
					O Patient taking as prescribed
Code:					O Patient taking but at a different dose or frequency
					O Patient not taking now
					O Patient taking as prescribed
Code:					O Patient taking but at a different dose or frequency
					O Patient not taking now
					O Patient taking as prescribed
 Code:					O Patient taking but at a different dose or frequency
					O Patient not taking now
					O Patient taking as prescribed
 Code:					O Patient taking but at a different dose or frequency
					O Patient not taking now





B. Contacts and <u>Antihypertensive</u> Medication Changes Documented in the Medical Record since the Last Study Visit with the Study Coordinator

Do not complete this section at the Baseline Study Visit. At all subsequent study visits, please record each contact that occurred since the last scheduled study visit with the study coordinator (including contacts unrelated to hypertension). Items B.1 – B.5 are always completed for every contact. **Table B.6 is only completed if there is a change** to an antihypertensive medication at the contact (as compared to Item A.2 (table) at the last study visit). If there are **no changes** to the antihypertensive medications at the contact, only complete Items B.1 - B.5.

1. Date of Conta	act:// (mm/dd/yyyy)	 Contact Type Hypertension Other visit Phone call 	 Contact with (check all that apply) a. Nurse/CMA b. Physician c. Pharmacist 	
4. Recommende	ed lifestyle change options (check all that	at apply):		5. ↑ BP medication compliance
\Box a. \downarrow weight	\Box b. DASH plan \Box c. \downarrow sodium	\Box d. Other diet recommendation	\Box e. \uparrow activity	recommended
\Box f. \downarrow smoking	🗌 g. Other	🗆 h. No	lifestyle changes	○ Yes ○ No
	g.1 Specify:	re	commended	\bigcirc 100

6. Medication Changes:

a. Medication	b. Change Type	c. Unit Strength	d. Dose	e. Frequency	f. PRN
 Code:	O Start New DrugO Decrease DoseO Discontinue DrugO Regimen Change (same dose)O Increase Dose				
 Code:	O Start New DrugO Decrease DoseO Discontinue DrugO Regimen Change (same dose)O Increase Dose				
 Code:	O Start New DrugO Decrease DoseO Discontinue DrugO Regimen Change (same dose)O Increase Dose				
 Code:	O Start New DrugO Decrease DoseO Discontinue DrugO Regimen Change (same dose)O Increase Dose				

10. SYMPTOM ASSESSMENT SCALE Subject ID: ____ - ___ __ Page **1** of **4**



Visit: O Baseline O 9 months

 \bigcirc 24 months

A. Visit Date: __/__/___ (mm/dd/yyyy)

INSTRUCTIONS (to be read to the subject):

The following questions ask about symptoms you might be experiencing. Each question begins, "In the past 4 weeks, how much have you been bothered by ______" and is followed by a symptom. Please select a number from 0 to 4 that reflects **how much the symptom has bothered you**, where 0 indicates that the symptom has not bothered you at all, 1 indicates that it has bothered you a little bit, 2 indicates it has bothered you somewhat, 3 indicates it has bothered you quite a bit and 4 indicates it has bothered you very much.

B. In the past 4 weeks how much have you been bothered by	Not at All [0]	A Little Bit [1]	Some- what [2]	Quite A Bit [3]	Very Much [4]
1. Feeling fatigued or tired	0	1	2	3	4
2. Feeling confused or disoriented	0	1	2	3	4
3. Feeling irritable or easily annoyed	0	1	2	3	4
4. Feeling fidgety or restless	0	1	2	3	4
5. Feeling anxious or nervous	0	1	2	3	4
6. Forgetfulness or memory problems	0	1	2	3	4
7. Seeing things or hearing things not really there (hallucinations)	0	1	2	3	4
8. Feeling sad or down in the dumps	0	1	2	3	4
9. Problems concentrating	0	1	2	3	4
10. Feeling drowsy or sleepy	0	1	2	3	4
11. Trouble getting to sleep or staying asleep	0	1	2	3	4
12. Feeling dizzy or woozy	0	1	2	3	4



C. In the past 4 weeks how much have you been bothered by	Not at All [0]	A Little Bit [1]	Some- what [2]	Quite A Bit [3]	Very Much [4]
1. Tremor or shakiness in your hands	0	1	2	3	4
2. Feeling that your muscles are weak	0	1	2	3	4
3. Decreased coordination or feeling clumsy	0	1	2	3	4
4. Pain, aches, or stiffness in your joints	0	1	2	3	4
5. Muscle aches, pain, or soreness	0	1	2	3	4
6. Back Pain	0	1	2	3	4
7. Falls	0	1	2	3	4

D. In the past 4 weeks how much have you been bothered by	Not at All [0]	A Little Bit [1]	Some- what [2]	Quite A Bit [3]	Very Much [4]
1. Difficulty breathing when resting	0	1	2	3	4
2. Difficulty breathing with usual activities	0	1	2	3	4
3. A cough	0	1	2	3	4
4. The feeling that your heart is beating strongly or quickly (palpitations)	0	1	2	3	4
5. Feeling dizzy or lightheaded when sitting up or standing up	0	1	2	3	4
6. Chest pain or tightness in your chest	0	1	2	3	4



E. In the past 4 weeks how much have you been bothered by	Not at All [0]	A Little Bit [1]	Some- what [2]	Quite A Bit [3]	Very Much [4]
1. Dry mouth	0	1	2	3	4
 Feeling like there is sand in your eyes, irritated eyes or dry eyes 	0	1	2	3	4
3. Blurry vision	0	1	2	3	4
4. Ringing in your ears	0	1	2	3	4
5. Changes in how foods taste or an unusual taste sensation (for example a metallic taste)	0	1	2	3	4
6. Difficulty swallowing	0	1	2	3	4
7. A stuffy or congested nose	0	1	2	3	4
8. Headaches	0	1	2	3	4

F. In the past 4 weeks how much have you been bothered by	Not at All [0]	A Little Bit [1]	Some- what [2]	Quite A Bit [3]	Very Much [4]
1. Constipation or hard stools	0	1	2	3	4
2. Diarrhea or loose stools	0	1	2	3	4
3. An upset stomach or nausea	0	1	2	3	4
4. Heartburn, sour taste in your mouth, or reflux	0	1	2	3	4
5. A decrease in appetite or not feeling like eating	0	1	2	3	4



G. In the past 4 weeks how much have you been bothered by	Not at All [0]	A Little Bit [1]	Some- what [2]	Quite A Bit [3]	Very Much [4]	
1. Leaking of urine or incontinence	0	1	2	3	4	
2. Difficulty urinating or starting to urinate	0	1	2	3	4	
 Frequent urination during the day or at night 	0	1	2	3	4	
4. Problems with having or enjoying sexual intercourse	0	1	2	3	4	Does Not Apply

H. In the past 4 weeks how much have you been bothered by	Not at All [0]	A Little Bit [1]	Some- what [2]	Quite A Bit [3]	Very Much [4]
1. Swelling in your feet, legs, or hands	0	1	2	3	4
2. Numbness or loss of feeling in your feet, legs, or hands	0	1	2	3	4
3. Tingling or pins and needles sensation in your feet, legs, or hands	0	1	2	3	4
4. A skin rash	0	1	2	3	4
5. Increased or unusual bruising of your skin	0	1	2	3	4



11. ASTHMA DEMOGRAPHIC Subject ID: _____- _ ____ Page **1** of **2**



1. Visit Date: _ _/_ _/_ _ (mm/dd/yyyy)

INSTRUCTIONS (to be read to the subject):

"The first questions ask for some basic information about you."

(Research nurse is to check the box corresponding to the subject's answers.)

- 2. Birth Date: __/_ /_ __ (mm/dd/yyyy)
- 3. Gender
 - O Male
 - Female
- 4. Race (check all that apply)
 - a. American Indian or Alaska Native
 - 🗌 b. Asian
 - C. Native Hawaiian or other Pacific Islander
 - □ d. Black or African-American
 - e. White
 - \Box f. Declined to answer
- 5. Ethnicity
 - O Hispanic or Latino
 - O Non-Hispanic or Non-Latino Origin
 - O Declined to Answer
- 6. Education (Select the highest grade completed or degree/certificate received.)
 - \bigcirc 1 5 years
 - $\bigcirc 6-8$ years
 - \bigcirc 9 12 years
- Master's degree
 Doctoral degree

○ 4-year BA or BS degree

O Post-high school technical /associate degree or certificate

- 7. Insurance Status (Select only the primary insurer.)
 - O Private insurance
 - O Medicare
 - O Medicaid
 - O Other insurer
 - O None/Self-pay
 - O Free care
- 8. Insurance Coverage for Prescriptions
 - O Yes
 - O No

Source Document Completed copy must be maintained in subject's study file ASTHMA

11. ASTHMA DEMOGRAPHIC Subject ID: _____- _____ Page **2** of **2**



- 9. Annual Household Income
 - <\$10,000
 - \$10, 000-\$24, 999
 - \$25,000- \$39,999
 - \$40,000-\$54,999
- 10. Marital Status
 - O Never married
 - O Married
 - O Living as married
 - O Divorced or separated
 - Widowed
- 11. Smoking Status
 - O Currently smokes (If 'Currently smokes' is selected, skip question 11.c)
 - O Former smoker
 - O Never smoked (If 'Never smoked' is selected, skip questions 11.a 11.c)
 - a. Number of years smoked:
 - b. Number of cigarettes smoked per day:
 - c. Elapsed time since quitting
 - \bigcirc < 5 years
 - 5-14 years
 - $\bigcirc \ge 15$ years
- 12. Current Alcohol Intake
 - O None
 - \bigcirc < 1 drink per day
 - O 1-2 drinks per day
 - 3-4 drinks per day
 - \bigcirc > 4 drinks per day
- 13. Duration of Asthma
 - O New diagnosis
 - \bigcirc < 6 months
 - O 6 months 1 year
 - \bigcirc >1 3 years
 - \bigcirc >3 5 years
 - >5 10 years
 - \bigcirc >10 years
- 14. Asthma Diagnosis
 - O Persistent asthma (not otherwise classified)
 - O Mild persistent asthma
 - O Moderate persistent asthma
 - O Severe persistent asthma

Source Document

○ \$55,000-\$79,999
 ○ \$80,000-\$99,999
 ○ >\$100,000
 ○ Refused to answer



12. ASTHMA CONTROL TEST Subject ID: ____ - ___ Page 1 of 1



- A. Date Administered: __/_ /_ __ (mm/dd/yyyy)
- B. Asthma Control Test
 - 1. In the <u>past 4 weeks</u>, how much of the time did your <u>asthma</u> keep you from getting as much done at work, school, or at home?
 - \bigcirc All of the time (1)
 - \bigcirc Most of the time (2)
 - $\bigcirc Some of the time \qquad (3)$
 - \bigcirc A little of the time (4)
 - \bigcirc None of the time (5)
 - 2. During the past 4 weeks, how often have you had shortness of breath?

(2)

- O More than once a day (1)
- O Once a day
- \bigcirc 3 to 6 times a week (3)
- \bigcirc Once or twice a week (4)
- \bigcirc Not at all (5)
- 3. During the <u>past 4 weeks</u>, how often did your <u>asthma</u> symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?
 - \bigcirc 4 or more nights a week (1)
 - \bigcirc 2 to 3 nights a week (2)
 - $\bigcirc \text{ Once a week} \tag{3}$
 - \bigcirc Once or twice (4)
 - \bigcirc Not at all (5)
- 4. During the <u>past 4 weeks</u>, how often have you used your rescue inhaler or nebulizer medication (such as Albuterol)?
 - \bigcirc 3 or more times per day (1)
 - \bigcirc 1 or 2 times per day (2)
 - \bigcirc 2 or 3 times per week (3)
 - \bigcirc Once a week or less (4)
 - \bigcirc Not at all (5)
- 5. How would you rate your <u>asthma</u> control during the <u>past 4 weeks</u>?
 - \bigcirc Not controlled at all (1)
 - \bigcirc Poorly controlled (2)
 - \bigcirc Somewhat controlled (3)
 - \bigcirc Well controlled (4)
 - \bigcirc Completely controlled (5)
- C. Total Score _____

13. ASTHMA MEDICAL RECORD ABSTRACTION Subject ID: _____- - _____ Page 1 of 1



Visit: O Baseline

- O 9 months
 - O 18 months

1. Date of Study Visit: __/_ /_ __ (mm/dd/yyyy)

2. Clinic Visits Documented in the Medical Record in the Past 9 Months:

a. Clinic Date	b. Visit Type	c. Visit to (check all that apply)	d. Corticosteroids Prescribed?	e. Duration of steroid course (days)
//	O Asthma O Other	 Emergency Dept. Clinic Visit Hospitalization 	O Yes O No	
//	O Asthma O Other	 Emergency Dept. Clinic Visit Hospitalization 	O Yes O No	
//	O Asthma O Other	 Emergency Dept. Clinic Visit Hospitalization 	O Yes O No	
//	O Asthma O Other	 Emergency Dept. Clinic Visit Hospitalization 	O Yes O No	
//	O Asthma O Other	 Emergency Dept. Clinic Visit Hospitalization 	O Yes O No	
//	O Asthma O Other	 Emergency Dept. Clinic Visit Hospitalization 	O Yes O No	



Visit:	Ο	Baseline
	Ο	9 months
	Ο	18 months

- A. Visit Date: __/_ /_ __ (mm/dd/yyyy)
- B. Medication Adherence

1.	Check medical record prior to visit: Does the subject have at least one active prescription for an asthma medication? (If NO, stop here and do NOT ask remaining questions.)	O Yes	O No
2.	Is the <u>only</u> prescribed asthma medication a rescue inhaler? (If YES, stop here and do NOT ask remaining questions.)	O Yes	O No
3.	Some people have difficulty in taking asthma medication as prescribed. Do you have difficulty with this?	O Yes	O No
4.	How many days in the past week did you forget to take your asthma medication?		days
5.	How many days in the past week did you <u>not</u> take your medication on purpose?		days
6.	How many days in the past week did you add an extra pill or puff other than your rescue inhaler (e.g. albuterol)?	_	days
7.	In the last 6 months, did you ever take less medicine because you felt you needed less (other than your rescue inhaler)?	O Yes	O No
8.	In the last 6 months, if you felt worse when you took the medicine, did you ever stop taking it?	O Yes	O No

ASTHMA

Version 2.0 01/Jan/2010 15. ASTHMA MEDICATIONS Subject ID: ____ - ___ __ Page 1 of 1



- Study Visit: O Baseline O 9 months O 18 months
- 1. Date of Study Visit: __/_ /_ __ (mm/dd/yyyy)
- 2. <u>Asthma</u> Medications Currently Prescribed at the Time of the Study Visit (to be completed at each study visit):

<u>INSTRUCTIONS (to be read to the subject)</u>: "I have a list of the asthma medications that we think you are taking. Please tell me how much of each medication you are taking or if you are not taking the medication."

a. Medication	b. Unit Strength	c. Dose	d. Frequency	e. PRN	f. Patient Report on Adherence
					O Patient taking as prescribed
					O Patient taking but at a different dose or frequency
Code:					O Patient not taking now
					O Patient taking as prescribed
					O Patient taking but at a different dose or frequency
Code:					O Patient not taking now
					O Patient taking as prescribed
					O Patient taking but at a different dose or frequency
Code:					O Patient not taking now
					O Patient taking as prescribed
					O Patient taking but at a different dose or frequency
Code:					O Patient not taking now
					O Patient taking as prescribed
					O Patient taking but at a different dose or frequency
Code:					O Patient not taking now



ASTHMA

16. ASTHMA PHARMACIST ENCOUNTER Subject ID: ____ - ___ __ Page 1 of 4



Subject Name: ______ (For site use only; do not enter into database.)

- A. PHARMACIST ENCOUNTER
- 1. Encounter Date: __/_ /_ __ (mm/dd/yyyy)
- 2. Contact Type:
 - O Initial
 - Follow-up
 - O Phone Communication
- 3. Pharmacist Code: _____
- 4. Asthma Medications (list ONLY asthma medications that are documented as current in the medical record):

a. Medication	b. Unit Strength	c. Dose	d. Frequency	e. PRN	f. Patient Report on Adherence
				_	O Patient taking as prescribed
Code:					O Patient taking but at a different dose or frequencyO Patient not taking now
 Code:					O Patient taking as prescribedO Patient taking but at a different dose or frequencyO Patient not taking now
 Code:					O Patient taking as prescribedO Patient taking but at a different dose or frequencyO Patient not taking now
 Code:					O Patient taking as prescribedO Patient taking but at a different dose or frequencyO Patient not taking now
 Code:					O Patient taking as prescribedO Patient taking but at a different dose or frequencyO Patient not taking now



ASTHMA

Version 2.1 28/Feb/2011

16. ASTHMA PHARMACIST ENCOUNTER Subject ID: ____ - ___ -Page 2 of 4

- 5. Recommended lifestyle change options (check all that apply):
 - \Box a. \downarrow weight
 - d. Other
 - d.1 Specify: _____
- 7. New Plan/Recommendations
 - O Continue current regimen
 - O Recommend change to plan (List changes to plan in Item A.8)

 \Box b. \downarrow smoking

8. Recommended Change to Plan:

a. Medication	b. Change Type	c. Unit Strength	d. Dose	e. Frequency	f. PRN	g. Comments	h. Physician Decision
Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 						O Accept O Reject O Modify
Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 						O Accept O Reject O Modify
Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 						O Accept O Reject O Modify
Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 						O Accept O Reject O Modify

in subject's study file

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ASTHMA



recommended

O Yes

O No

- \Box c. Avoid allergen(s)
- e. No lifestyle changes
- - recommended

16. ASTHMA PHARMACIST EI Subject ID: Page 3 of 4					Collaboration Among Pharmacists and Physicians To Improve Outcomes Now
9. Planned Follow-up w	vith Pharmacist (check a	ll that apply):			
🗌 a. 1 week	🗌 b. 2 weeks	🗌 c. 4 weeks	🗌 d. 6 weeks	🗌 e. 8 weeks	☐ f. 3 months
☐ g. Other time g.1 Spec					

□ h. Patient declined to re-schedule

i. Pharmacist intervention completed

10. Final Plan (Complete only if changed from pharmacist recommended plan):

a. Medication	b. Change Type	c. Unit Strength	d. Dose	e. Frequency	f. PRN
 Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 				
 Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 				
 Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 				
 Code:	 O Start New Drug O Discontinue Drug O Increase Dose O Decrease Dose O Regimen Change (same dose) 				



ASTHMA

16. ASTHMA PHARMACIST ENCOUNTER Subject ID: _____- - _____ Page 4 of 4



B. PHARMACIST TIME DOCUMENTATION

1. Start time: _____ (use military time, e.g. 1645)

2. End time: _____ (use military time, e.g. 1645)

Please complete the following by estimating the number of minutes you spent doing each activity.

3. Activity	Minutes to complete activity (circle one)
a. Medical record review prior to patient visit	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
b. Consultation with other provider or family	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
c. Patient assessment/medication history	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
d. Medical record review during patient visit	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
e. Order laboratory	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
f. Order medications/write prescriptions	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
g. Medical education	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
h. Lifestyle modification education	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
i. Education on inhaler technique or peak flow measure	ment 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
j. Recommendations to MD	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA
k. Documentation in medical record	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 >30 NA

Please use the following CPT codes to code medication therapy management service(s) provided during the visit by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided:

- 99605 Initial 15 minutes, *new* patient
- 99606 Initial 15 minutes, established patient
- **99607** Each *additional* 15 minutes (Use 99607 in conjunction with 99605, 99606; code separately in addition to code for primary service.)

CPT code for initial 15 minutes:

Baseline encounter = 99605 (new patient) Encounters after Baseline = 99606 (established patient)

4. Number of 15 minute units of CPT code 99607 (1=15 additional minutes, 2=30 additional minutes, 3=45 additional minutes, etc.):



ASTHMA

Version 2.1 28/Feb/2011



Visit: O Baseline O 9 months O 18 months

A. Visit Date: __/__/___(mm/dd/yyyy)

B. Self Report

- 1. Courses of oral corticosteroids (e.g. prednisone) in past 9 months: _____
- 2. Number of days on oral corticosteroids (e.g. prednisone) in past 9 months: _____
- 3. Number of hospitalizations due to asthma in the past 9 months: _____
- Number of emergency room visits due to asthma in the past 9 months: _____
- 5. Number of doctor's office visits due to asthma in the past 9 months: _____
- 6. Number of days of school or work missed due to asthma in the past 9 months: _____ For subjects not currently working or attending school, this question should be "Number of days that asthma was severe enough that you would have missed work or school in the past 9 months: _____"



ASTHMA

Version 1.0 01/Sep/2009 18. ASTHMA QUALITY OF LIFE QUESTIONNAIRE Subject ID: _____- - ____ ___ Page 1 of 2



Visit: O Baseline O 9 months

○ 18 months

A. Visit Date: __/_ _/_ _ _ (mm/dd/yyyy)

INSTRUCTIONS (to be read to the subject):

The following questions ask about how asthma may be affecting your daily life. Each question begins, "In the past 4 weeks, how much have you ______" and is followed by a situation or feeling. Please select a number from 0 to 3 that reflects **how much the situation or feeling has happened to you in the past 4 weeks**, where 0 indicates that the situation or feeling has not happened at all, 1 indicates that it has happened a little, 2 indicates it has happened somewhat, and 3 indicates it has happened a great deal in the past 4 weeks.

B. QUESTIONNAIRE

In the past 4 weeks how much have you	Not at All	A Little	Somewhat	A Great Deal
Joann	[0]	[1]	[2]	[3]
 Been troubled by episodes of shortness of breath 	0	1	2	3
2. Been troubled by wheezing attacks	0	1	2	3
 Been troubled by tightness in the chest 	0	1	2	3
 Been restricted in walking down the street on level ground or doing light housework because of asthma 	0	1	2	3
 Been restricted in walking up hills or doing heavy housework because of asthma 	0	1	2	3
6. Felt tired or a general lack of energy	0	1	2	3
7. Been unable to sleep at night	0	1	2	3
8. Felt sad or depressed	0	1	2	3
9. Felt frustrated with myself	0	1	2	3

ASTHMA



In the past 4 weeks how much have	Not at All	A Little	Somewhat	A Great Deal
you	[0]	[1]	[2]	[3]
10. Felt anxious, under tension, or stressed	0	1	2	3
11. Felt that asthma is preventing me from achieving what I want from life	0	1	2	3
12. Felt that asthma has interfered with my social life	0	1	2	3
13. Been limited in going certain places because they are bad for my asthma	0	1	2	3
14. Been limited in going to certain places because I have been afraid of having an asthma attack and not being able to get help	0	1	2	3
15. Felt generally restricted	0	1	2	3
16. Been restricted in the sports, hobbies, or other recreations I can engage in because of my asthma	0	1	2	3
17. Felt that asthma is controlling my life	0	1	2	3
18. Been worried about my present or future life because of asthma	0	1	2	3
19. Been worried about asthma shortening my life	0	1	2	3
20. Felt dependent on my asthma inhalers	0	1	2	3

19. PASSIVE MEDICAL RECORD ABSTRACTION Subject ID: _____- - ____ Page 1 of 4



- 1. Date of index clinic visit: ___/__/ __/ ___ (mm/dd/yyyy)
- 2. Primary physician code Not applicable

SUBJECT DEMOGRAPHIC DATA

- 3. Birth Date: ___/__/ ___ (mm/dd/yyyy)
- 4. Gender
 - O Male
 - O Female
- 5. Race (check all that apply)
 - a. American Indian or Alaska Native
 - 🗆 b. Asian
 - □ c. Native Hawaiian or other Pacific Islander
 - □ d. Black or African-American
 - a. White
 - ☐ f. Unknown/not reported
- 6. Ethnicity
 - O Hispanic or Latino
 - O Non-Hispanic or Non-Latino Origin
 - O Unknown/not reported
- 7. Height: ____ . ___ a. O centimeters
- 8. Weight: ____ . ___ a. O kilograms

O pounds

O inches

□ Not Documented

Not Documented

- 9. Type of Health Insurance (check all that apply)
 - □ b. Medicare
 - C. Medicaid
 - d. Other insurer
 - □ e. None (self-pay)
 - f. Free care
 - □ g. Not documented
- 10. Insurance Coverage for Prescriptions:
 - O Yes
 - O No
 - O Not documented
19. PASSIVE MEDICAL RECORD ABSTRACTION Subject ID: ____ - ___ ___ Page **2** of **4**



- 11. Smoking History
 - O Currently smokes
 - O Former smoker
 - O Never smoked
 - O Not documented
- 12. Current Alcohol Intake
 - O 0 (does not drink or drinks <1 alcoholic beverage/day)
 - O 1-2 drinks per day
 - O 3-4 drinks per day
 - O > 4 drinks per day
 - O Not documented
- 13. Diagnosed Conditions (check all that apply)
 - a. Diabetes
 - b. Chronic Kidney Disease
 - □ c. Coronary Artery Disease
 - □ d. Congestive Heart Failure
 - e. Hyperlipidemia
 - ☐ f. Stroke or TIA
 - g. Peripheral Artery Disease
 - h. Asthma or COPD
 - \Box i. Depression or anxiety
 - ☐ j. Arthritis/DJD/Chronic Pain
 - k. Seizures/Other Neurological Disorder
 - □ I. Liver Disease
 - □ m. None of the above
- 14. Two most recent serum creatinine values prior to index clinic visit:
 - a. First most recent serum creatinine test
 - i. Value: ____
 - ii. Date drawn: ___/__/__ __ (mm/dd/yyyy)
 - b. Second most recent serum creatinine test
 - i. Value: ____
 - ii. Date drawn: ___/__/___ (mm/dd/yyyy)



HYPERTENSIVE MEDICATIONS AND BLOOD PRESSURE AT INDEX, 9 MONTH, AND 24 MONTH VISITS

15. Index Clinic Visit

- a. Date of visit: ___/__/_ __/ (mm/dd/yyyy)
- b. Clinic blood pressure
 - i. Systolic: _____
 - ii. Diastolic: _____
- c. Prescribed hypertension medications

Medication:	Medication:
Code:	Code:
Medication:	Medication:
Code:	Code:
Medication:	Medication:
Code:	Code:

16. 9 months after Index Visit

(Select the visit closest to 9 months that is no earlier than 6 months and no more than 12 months after the Index Visit.)

- a. Date of visit: ___/__/_ __/ (mm/dd/yyyy)
- b. Clinic blood pressure
 - i. Systolic: ___ __
 - ii. Diastolic: _____

c. Prescribed hypertension medications

Medication:	Medication:
Code:	Code:
Medication:	Medication:
Code:	Code:
Medication:	Medication:
Code:	Code:

19. PASSIVE MEDICAL RECORD ABSTRACTION Subject ID: ____ - ___ _ Page 4 of 4



17. 24 months after Index Visit

(Select the visit closest to 24 months that is no earlier than 21 months and no more than 27 months after the Ìndex Visit.)

- a. Date of visit: ___/__/_ __/ (mm/dd/yyyy)
- b. Clinic blood pressure

 - i. Systolic: __ __ __ ii. Diastolic: __ __ __
- c. Prescribed hypertension medications

Medication:	Medication:
Code:	Code:
Medication:	Medication:
Code:	Code:
Medication:	Medication:
Code:	Code:



Please read each question carefully and answer it to the best of your ability. There are no correct or incorrect responses; we are merely interested in your point of view. The questionnaire may appear to be monotonous since several of the statements are worded in a repetitive manner. However, the scientific nature of the study requires this methodological approach. Your collaboration is vital to the success of this project. <u>It is important to get your opinion</u>.

Description and Definition: Think about the physicians in your medical office with whom you work closely. When we use the term **physician\pharmacist collaborative model (PPCM)** we mean an interdependent relationship with the following characteristics. First, the physician would ask you to see a patient to: 1) assess the patient and their medications, 2) determine the barriers to achieving goals of care, 3) develop a care plan and recommend that plan to the physician, 4) if the physician agrees with the plan, you have the responsibility to implement the plan, which may require you to provide: a) dosage titrations and medication changes, and b) more frequent office visits with you to titrate medications, educate the patient, and monitor for side effects, and 5) you communicate the changes with the physician, especially for complex issues that require physician oversight and collaboration. This process continues until the patient's goals of care are met.

- A. QUESTIONNAIRE
- 1. Think about the last 10 patients you were aware of in your medical office whose asthma was not controlled (required frequent emergency department visits). How many patients did physicians refer to you to provide PPCM as defined above?

(circle one number).....0 1 2 3 4 5 6 7 8 9 10

2. I expect to provide PPCM for patients in our practice who have uncontrolled asthma.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

3. I want to provide PPCM for patients in our practice who have uncontrolled asthma.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

4. I intend to provide PPCM for patients in our practice who have uncontrolled asthma.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Scenario 1: A patient is visiting one of your physicians today for the fourth time since her last annual physical she had a year ago. She is a 44 year old, happily married, black female. Her H&P is noncontributory except for a diagnosis of persistent asthma. The physician has tried multiple combinations of medications but she has still been to the emergency room twice in the last 6 months for severe shortness of breath. The physician believes she is taking her medications as prescribed. The physician wants you to provide PPCM.

5. Your decision: Will you provide PPCM for this person? O YES O NO

6. On the scale of 1 to 7, how difficult will it be for you to provide PPCM for this patient?

Not difficult at all 1 2 3 4 5 6 7 Extremely Difficult

7. People who are important to me professionally think that I should provide PPCM for this patient.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

20. MANAGING CHRONIC CONDITIONS SURVEY (PHARMACIST) Provider Code: _____ - ___ ___ Page 2 of 5



8. I am confident that I can provide PPCM for this patient.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

9. I think that administrators in my clinic/health system that care about quality improvement would approve of me providing PPCM for this patient.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

10. I think most ambulatory care pharmacy specialists would approve of me providing PPCM for this patient. Strongly disagree 1 2 3 4 5 6 7 Strongly agree

11. I feel capable of providing PPCM for this patient.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Scenario 2: Another patient with asthma and depression is visiting your office today. The physician sees him about once every 6 months for his depression which is fairly well controlled. He is 19 years old, overweight and smokes 5-10 cigarettes daily. He has no other problems. Over the past six months his asthma control has been deteriorating with a visit to the emergency room a few weeks ago. He uses Advair 500/50 1 puff BID and Albuterol HFA 2 puffs q4h prn.

12. Your decision: Will you provide PPCM for this person if referred by the physician?

O YES O NO

13. On the scale of 1 to 7, how difficult will it be for you to provide PPCM for this patient?

Not difficult at all 1 2 3 4 5 6 7 Extremely Difficult

14. For me, providing PPCM for the patient in Scenario 2 would be:

a.	Helpful	1	2	3	4	5	6	7	Unhelpful
b.	Necessary	1	2	3	4	5	6	7	Unnecessary
C.	Satisfying	1	2	3	4	5	6	7	Not satisfying

15. Think about the last 10 patients you were aware of in your medical office whose BP was not controlled (≥140/90 mm Hg if uncomplicated or ≥130/80 mm Hg with diabetes). How many patients did physicians refer to you to provide PPCM as defined above? (circle one number).....0 1 2 3 4 5 6 7 8 9 10

16. I expect to provide PPCM for patients in our practice who have uncontrolled BP.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

17. I want to provide PPCM for patients in our practice who have uncontrolled BP.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

18. I intend to provide PPCM for patients in our practice who have uncontrolled BP. Strongly disagree 1 2 3 4 5 6 7 Strongly agree



Scenario 3: A patient is visiting one of your physicians today for the fourth time since her last annual physical she had a year ago. She is a 72 year old, happily married, retired black female. Her H&P is noncontributory except for a diagnosis of hypertension. The physician has tried several medications and combinations of medications but her BP remains 158/82 mm Hg. The physician believes she is taking her medications as prescribed. The physician wants you to provide PPCM												
19. Your decision: Will you provide PPCM for this person? O YES O NO												
20. On the scale of 1 to 7, how difficult will it be for you to provide PPCM for this patient?												
Not difficult at all 1 2 3 4 5 6 7 Extremely Difficult												
21. People who are important to me professionally think that I should provide PPCM for this patient. Strongly disagree 1 2 3 4 5 6 7 Strongly agree												
22. I am confident that I can provide PPCM for this patient.												
Strongly disagree 1 2 3 4 5 6 7 Strongly agree												
23. I think that administrators in my clinic/health system that care about quality improvement would approve of me providing PPCM for this patient.												
Strongly disagree 1 2 3 4 5 6 7 Strongly agree												
24. I think most ambulatory care pharmacy specialists would approve of me providing PPCM for this patient. Strongly disagree 1 2 3 4 5 6 7 Strongly agree												
25. I feel capable of providing PPCM for this patient.												
Strongly disagree 1 2 3 4 5 6 7 Strongly agree												
<u>Scenario 4</u> : Another patient with hypertension and diabetes visits your office today. The physician sees him about once every 3 months for his diabetes which is fairly well controlled. He is 56 years old, overweight and he does not smoke. He has no other problems except osteoarthritis of the knees. Over the past six months his BP has slowly increased from 122/74 to 134/84 mm Hg. He takes maximum doses of lisinopril for his BP and renal protection.												
26. Your decision: Will you provide PPCM for this person if referred by the physician? O YES O NO												
27. On the scale of 1 to 7, how difficult will it be for you to provide PPCM for this patient?												
Not difficult at all 1 2 3 4 5 6 7 Extremely Difficult												

28. For me, providing PPCM for the patient in Scenario 4 would be:

a. Help	ful 1	2	3	4	5	6	7	Unhelpful
b. Nece	essary 1	2	3	4	5	6	7	Unnecessary
c. Satis	sfying 1	2	3	4	5	6	7	Not satisfying



Consider your working relationship with a physician with whom you work the most. Think, in general, about the interactions you've had with this physician over time (not just for asthma or hypertension). Please indicate your agreement with each of the following statements by using the scale listed below. Please circle the number that represents your agreement with the item.

SCALE: 1-Very Strongly Disagree 2-Strongly Disagree 3-Disagree 4-Neutral 5-Agree 6-Strongly Agree 7-Very Strongly Agree

29. In providing patient care, the physician needs me as much as I need this physician.	1	2	3	4	5	6	7
30. The physician is credible.	1	2	3	4	5	6	7
31. My interactions with this physician are characterized by open communication of both parties.	1	2	3	4	5	6	7
32. I can count on this physician to do what he/she says.	1	2	3	4	5	6	7
33. This physician depends on me as much as I depend on him/her.	1	2	3	4	5	6	7
34. This physician and I are mutually dependent on each other in caring for patients.	1	2	3	4	5	6	7
35. This physician and I negotiate to come to agreement on our activities in managing drug therapy.	1	2	3	4	5	6	7
36. I will work with this physician to overcome disagreements on his/her role in managing drug therapy.	1	2	3	4	5	6	7
37.I intend to keep working together with this physician.	1	2	3	4	5	6	7
38. I trust this physician's medical expertise.	1	2	3	4	5	6	7
39. Communication between this physician and myself is two-way.	1	2	3	4	5	6	7

SCALE: 1=Not at all---5=To a great extent

Please indicate the extent to which this physician has.....

40. Spent time trying to learn how he/she can help you provide better care	1	2	3	4	5
41. Provided information to you about a specific patient	1	2	3	4	5
42. Showed an interest in helping you improve your practice	1	2	3	4	5

20. MANAGING CHRONIC CONDITIONS SURVEY (PHARMACIST) Provider Code: _____ - ___ ___ Page 5 of 5



- B. PHARMACIST DEMOGRAPHIC INFORMATION
 - 1. Birth Date: __/_ _/_ __ (mm/dd/yyyy)
 - 2. Gender
 - O Male
 - Female
 - 3. Race (check all that apply)
 - □ a. American Indian or Alaska Native
 - □ b. Asian
 - □ c. Native Hawaiian or other Pacific Islander
 - □ d. Black or African-American
 - e. White
 - \Box f. Declined to Answer
 - 4. Ethnicity
 - O Hispanic or Latino
 - O Non-Hispanic or Non-Latino Origin
 - O Declined to Answer
 - 5. Do you speak Spanish?
 - O Yes O No
 - 6. Academic Affiliation:
 - O Resident or Fellow
 - Full-time Faculty Appointment
 - O Part-time/Adjunct Faculty Appointment
 - O Not academically affiliated
 - 7. How long have you practiced clinical pharmacy (excluding residency)? a. ___ years b. ___ months
 - 8. Degree, residency & certifications (check all that apply):
 - a. RPh
 - b. PharmD
 - □ c. Pharmacy Practice Residency
 - □ d. Am Care Specialty Residency
 - e. Fellowship
 - 🗌 f. BCPS
 - □ g. BCPP
 - h. BCOP
 - 🗌 i. CDE
 - ☐ j. Other
 - j.1 Specify: _____
 - 9. Number of ½ days per week you provide patient or clinical services: _____ ½ days (including time with students and residents)

Thank you for your time



Please read each question carefully and answer it to the best of your ability. There are no correct or incorrect responses; we are merely interested in your point of view. The questionnaire may appear to be monotonous since several of the statements are worded in a repetitive manner. However, the scientific nature of the study requires this methodological approach. Your collaboration is vital to the success of this project. It is important to get your opinion.

Description and Definition: Think about the physicians in your medical office with whom you work closely. When we use the term **physician\pharmacist collaborative model (PPCM)** for hypertension management we mean an interdependent relationship with the following characteristics. First, the physician would ask you to see a patient who is not at BP goal to: 1) assess the patient and their medications, 2) determine the barriers to achieving BP goal, 3) develop a care plan to get to BP goal and recommend that plan to the physician, 4) if the physician agrees with the plan you have the responsibility to implement the plan which may require the you to provide: a) dosage titrations and medication changes, and b) more frequent office visits with you to titrate medications, educate the patient, monitor for side effects, 5) and you communicate the changes with the physician, especially for complex issues that require physician oversight and collaboration. This process continues until the patient's BP is controlled.

- A. QUESTIONNAIRE
- Think about the last 10 patients you were aware of in your medical office whose BP was not controlled (≥140/90 mm Hg if uncomplicated or ≥130/80 mmHg with diabetes). How many patients did physicians refer to you to provide PPCM as defined above? (circle one number).....0 1 2 3 4 5 6 7 8 9 10
- I expect to provide PPCM for patients in our practice who have uncontrolled BP. Strongly disagree 1 2 3 4 5 6 7 Strongly agree
 I want to provide PPCM for patients in our practice who have uncontrolled BP. Strongly disagree 1 2 3 4 5 6 7 Strongly agree
 I intend to provide PPCM for patients in our practice who have uncontrolled BP. Strongly disagree 1 2 3 4 5 6 7 Strongly agree
 I intend to provide PPCM for patients in our practice who have uncontrolled BP. Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Scenario 1: A patient is visiting one of your physicians today for the fourth time since her last annual physical she had a year ago. She is a 72 year old, happily married, retired black female. Her H&P is noncontributory except for a diagnosis of hypertension. The physician has tried several medications and combinations of medications but her BP remains 158/82 mm Hg. The physician believes she is taking her medications as prescribed. The physician wants you to provide PPCM.

5. Your decision: Will you provide PPCM for this lady? O YES O NO

6. On the scale of 1 to 7, how difficult will it be for you to provide PPCM for this patient?

Not difficult at all 1 2 3 4 5 6 7 Extremely Difficult

7. People who are important to me professionally think that I should provide PPCM for this patient.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree



8. I am confident that I can provide PPCM for this patient.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

9. I think that administrators in my clinic/health system that care about quality improvement would approve of me providing PPCM for this patient.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

- 10. I think most ambulatory care pharmacy specialists would approve of me providing PPCM for this patient. Strongly disagree 1 2 3 4 5 6 7 Strongly agree
- 11. I feel capable of providing PPCM for this patient.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

<u>Scenario 2</u>: Another patient with hypertension and diabetes visits your office today. The physician sees him about once every 3 months for his diabetes which is fairly well controlled. He is 56 years old, overweight and he does not smoke. He has no other problems except osteoarthritis of the knees. Over the past six months his BP has slowly increased from 122/74 to 134/84 mm Hg. He takes maximum doses of lisinopril for his BP and renal protection.

12. Your decision: Will you provide PPCM for this man if referred by the physician? O YES O NO

13. On the scale of 1 to 7, how difficult will it be for you to provide PPCM for this patient?

Not difficult at all 1 2 3 4 5 6 7 Extremely Difficult

14. For me, providing PPCM for the patient in Scenario 2 would be:

a.	Helpful	1	2	3	4	5	6	7	Unhelpful
b.	Necessary	1	2	3	4	5	6	7	Unnecessary
c.	Satisfying	1	2	3	4	5	6	7	Not satisfying



Consider your working relationship with a physician with whom you work the most. Think, in general, about the interactions you've had with this physician over time (not just for hypertension). Please indicate your agreement with each of the following statements by using the scale listed below. Please circle the number that represents your agreement with the item.

SCALE: 1-Very Strongly Disagree 2-Strongly Disagree 3-Disagree 4-Neutral 5-Agree 6-Strongly Agree 7-Very Strongly Agree

15. In providing patient care, the physician needs me as much as I need this physician.	1	2	3	4	5	6	7
16. The physician is credible.	1	2	3	4	5	6	7
17. My interactions with this physician are characterized by open communication of both parties.	1	2	3	4	5	6	7
18. I can count on this physician to do what he/she says.	1	2	3	4	5	6	7
19. This physician depends on me as much as I depend on him/her.	1	2	3	4	5	6	7
20. This physician and I are mutually dependent on each other in caring for patients.	1	2	3	4	5	6	7
21. This physician and I negotiate to come to agreement on our activities in managing drug therapy.	1	2	3	4	5	6	7
22. I will work with this physician to overcome disagreements on his/her role in managing drug therapy.	1	2	3	4	5	6	7
23. I intend to keep working together with this physician.	1	2	3	4	5	6	7
24. I trust this physician's medical expertise.	1	2	3	4	5	6	7
25. Communication between this physician and myself is two-way.	1	2	3	4	5	6	7

SCALE: 1=Not at all---5=To a great extent

Please indicate the extent to which this physician has.....

26. Spent time trying to learn how he/she can help you provide better care	1	2	3	4	5	
27. Provided information to you about a specific patient	1	2	3	4	5	
28. Showed an interest in helping you improve your practice	1	2	3	4	5	

21. MANAGING HIGH BLOOD PRESSURE SURVEY (PHARMACIST) Provider Code: _____ - ___ ___ Page **4** of **4**



- B. PHARMACIST DEMOGRAPHIC INFORMATION
 - 1. Birth Date: __/_ _/_ __ (mm/dd/yyyy)
 - 2. Gender
 - O Male
 - Female
 - 3. Race (check all that apply)
 - a. American Indian or Alaska Native
 - □ b. Asian
 - □ c. Native Hawaiian or other Pacific Islander
 - □ d. Black or African-American
 - e. White
 - \Box f. Declined to Answer
 - 4. Ethnicity
 - O Hispanic or Latino
 - O Non-Hispanic or Non-Latino Origin
 - O Declined to Answer
 - 5. Do you speak Spanish?
 - O Yes O No
 - 6. Academic Affiliation:
 - O Resident or Fellow
 - Full-time Faculty Appointment
 - O Part-time/Adjunct Faculty Appointment
 - O Not academically affiliated
 - 7. How long have you practiced clinical pharmacy (excluding residency)? a. ___ years b. ___ months
 - 8. Degree, residency & certifications (check all that apply):
 - a. RPh
 - b. PharmD
 - □ c. Pharmacy Practice Residency
 - □ d. Am Care Specialty Residency
 - e. Fellowship
 - 🗌 f. BCPS
 - □ g. BCPP
 - h. BCOP
 - 🗌 i. CDE
 - ☐ j. Other
 - j.1 Specify: _____
 - 9. Number of ½ days per week you provide patient or clinical services: _____ ½ days (including time with students and residents)

Thank you for your time

22. MANAGING CHRONIC CONDITIONS SURVEY (PHYSICIAN) Provider Code: _____ - ____ Page 1 of 5



Please read each question carefully and answer it to the best of your ability. There are no correct or incorrect responses; we are merely interested in your point of view. The questionnaire may appear to be monotonous since several of the statements are worded in a repetitive manner. However, the scientific nature of the study requires this methodological approach. Your collaboration is vital to the success of this project. <u>It is important to get your opinion</u>.

Description and Definition: Think about the clinical pharmacist in your medical office. When we use the term **physician\pharmacist collaborative model (PPCM)** we mean an interdependent relationship with the following characteristics. First, you ask the pharmacist to see your patient to: 1) assess the patient and their medications, 2) the pharmacist determines the barriers to achieving goals of care, 3) develops a care plan and recommends that plan to you, 4) if you agree with the plan, you give the pharmacist responsibility to implement the plan, which may require the pharmacist to provide: a) dosage titrations and medication changes, and b) more frequent office visits with the pharmacist to titrate medications, educate the patient, and monitor for side effects, and 5) the pharmacist communicates the changes with you, especially for complex issues that require your oversight and collaboration. This process continues until all the goals of care are met.

- A. QUESTIONNAIRE
- Think about your last 10 patients whose asthma was not well controlled (required frequent emergency department visits). How many patients did you refer to the pharmacist to provide PPCM as defined above? (circle one number).....0 1 2 3 4 5 6 7 8 9 10
- 2. I expect to refer patients with uncontrolled asthma to the pharmacist who will then provide PPCM Strongly disagree 1 2 3 4 5 6 7 Strongly agree
- 3. I want to refer patients with uncontrolled asthma to the pharmacist who will then provide PPCM Strongly disagree 1 2 3 4 5 6 7 Strongly agree
- 4. I intend to refer patients with uncontrolled asthma to the pharmacist who will then provide PPCM Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Scenario 1: One of your patients is visiting you today for the fourth time since her last annual physical she had a year ago. She is a 44 year old, happily married, black female. Her H&P is noncontributory except for your diagnosis of persistent asthma. You have tried multiple combinations of medications but she has still been to the emergency room twice in the last 6 months for severe shortness of breath. As far as you can tell, she is taking her medications as you prescribe.

5. Your decision: Will you refer this person to your pharmacist for PPCM? O YES O NO

- On the scale of 1 to 7, how difficult will it be for you to refer this patient to the pharmacist? Not difficult at all 1 2 3 4 5 6 7 Extremely Difficult
- 7. People who are important to me professionally think that I should refer this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree



- 8. I am confident that I can refer this patient to the pharmacist to provide PPCM. Strongly disagree 1 2 3 4 5 6 7 Strongly agree
- 9. I think that administrators in my clinic/health system that care about quality improvement would approve of me referring this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

10. I think most primary care physicians would approve of me referring this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

11. I feel capable of referring this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Scenario 2: Another one of your patients with asthma and depression is visiting you today. You see him about once every 6 months for his depression which is fairly well controlled. He is 19 years old, overweight and smokes 5-10 cigarettes daily. He has no other problems. Over the past six months his asthma control has been deteriorating with a visit to the emergency room a few weeks ago. He uses Advair 500/50 1 puff BID and Albuterol HFA 2 puffs q4h prn.

12. Your decision: Will you refer this person to your pharmacist for PPCM? O YES O NO

13. On the scale of 1 to 7, how difficult will it be for you to refer this patient to the pharmacist? Not difficult at all 1 2 3 4 5 6 7 Extremely Difficult

14. For me, referring the patient in Scenario 2 to the pharmacist to provide PPCM would be:

a.	Helpful	1	2	3	4	5	6	7	Unhelpful
b.	Necessary	1	2	3	4	5	6	7	Unnecessary
C.	Satisfying	1	2	3	4	5	6	7	Not satisfying

- 15. Think about your last 10 patients whose BP was not controlled (>140/90 mm Hg if uncomplicated or >130/80 mmHg with diabetes). How many patients did you refer to the pharmacist to provide PPCM as defined above (circle one number).....0 1 2 3 4 5 6 7 8 9 10
- 16. I expect to refer patients with uncontrolled BP to the pharmacist who will then provide PPCM Strongly disagree 1 2 3 4 5 6 7 Strongly agree
- 17. I want to refer patients with uncontrolled BP to the pharmacist who will then provide PPCM Strongly disagree 1 2 3 4 5 6 7 Strongly agree
- 18. I intend to refer patients with uncontrolled BP to the pharmacist who will then provide PPCM Strongly disagree 1 2 3 4 5 6 7 Strongly agree



Scenario 3: One of your patients is visiting you today for the fourth time since her last annual physical she had a year ago. She is a 72 year old, happily married, retired black female. Her H&P is noncontributory except for your diagnosis of hypertension. You have tried several medications and combinations of medications but her BP remains 158/82 mm Hg. As far as you can tell, she is taking her medications as you prescribe.

19. Your decision: Will you refer this person to your pharmacist for PPCM? O YES O NO

20. On the scale of 1 to 7, how difficult will it be for you to refer this patient to the pharmacist? Not difficult at all 1 2 3 4 5 6 7 Extremely Difficult

21. People who are important to me professionally think that I should refer this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

22. I am confident that I can refer this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

23. I think that administrators in my clinic/health system that care about quality improvement would approve of me referring this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

24. I think most primary care physicians would approve of me referring this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

25. I feel capable of referring this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

<u>Scenario 4:</u> Another one of your patients with hypertension and diabetes is visiting you today. You see him about once every 3 months for his diabetes which is fairly well controlled. He is 56 years old, overweight and he does not smoke. He has no other problems except osteoarthritis of the knees. Over the past six months his BP has slowly increased from 122/74 to 134/84 mm Hg. He takes maximum doses of lisinopril for his BP and renal protection.

26. Your decision: Will you refer this person to your pharmacist for PPCM? O YES O NO

27. On the scale of 1 to 7, how difficult will it be for you to refer this patient to the pharmacist? Not difficult at all 1 2 3 4 5 6 7 Extremely Difficult

28. For me, referring the patient in Scenario 4 to the pharmacist to provide PPCM would be:

a.	Helpful	1	2	3	4	5	6	7	Unhelpful
b.	Necessary	1	2	3	4	5	6	7	Unnecessary
c.	Satisfying	1	2	3	4	5	6	7	Not satisfying



Consider your working relationship with a pharmacist with whom you work the most. Think, in general, about the interactions you've had with this pharmacist over time (not just for asthma or hypertension). Please indicate your agreement with each of the following statements by using the scale listed below. Please circle the number that represents your agreement with the item.

SCALE: 1-Very Strongly Disagree 2-Strongly Disagree 3-Disagree 4-Neutral 5-Agree 6-Strongly Agree 7-Very Strongly Agree

29. In providing patient care, I need this pharmacist as much as this pharmacist needs me.	1	2	3	4	5	6	7
30. The pharmacist is credible.	1	2	3	4	5	6	7
31. My interactions with this pharmacist are characterized by open communication of both parties.	1	2	3	4	5	6	7
32. I can count on this pharmacist to do what he/she says.	1	2	3	4	5	6	7
33. This pharmacist depends on me as much as I depend on him/her.	1	2	3	4	5	6	7
34. This pharmacist and I are mutually dependent on each other in caring for patients.	1	2	3	4	5	6	7
35. This pharmacist and I negotiate to come to agreement on our activities in managing drug therapy.	1	2	3	4	5	6	7
36. I will work with this pharmacist to overcome disagreements on his/her role in managing drug therapy.	1	2	3	4	5	6	7
37. I intend to keep working together with this pharmacist.	1	2	3	4	5	6	7
38. I trust this pharmacist's drug expertise.	1	2	3	4	5	6	7
39. Communication between this pharmacist and myself is two-way.	1	2	3	4	5	6	7

SCALE: 1=Not at all---5=To a great extent

Please indicate the extent to which this pharmacist has.....

40. Spent time trying to learn how he/she can help you provide better care	1	2	3	4	5	
41. Provided information to you about a specific patient	1	2	3	4	5	
42. Showed an interest in helping you improve your practice	1	2	3	4	5	

22. MANAGING CHRONIC CONDITIONS SURVEY (PHYSICIAN) Provider Code: ____ - __ __ __ Page **5** of **5**



- B. PHYSICIAN DEMOGRAPHIC INFORMATION
 - 1. Birth Date: __/_ _/_ __ (mm/dd/yyyy)
 - 2. Gender
 - \bigcirc Male
 - Female
 - 3. Race (check all that apply)
 - a. American Indian or Alaska Native
 - □ b. Asian
 - □ c. Native Hawaiian or other Pacific Islander
 - □ d. Black or African-American
 - e. White
 - \Box f. Declined to Answer
 - 4. Ethnicity
 - O Hispanic or Latino
 - O Non-Hispanic or Non-Latino Origin
 - O Declined to Answer
 - 5. Spanish Speaker
 - O Yes O No
 - 6. Academic Affiliation
 - O Resident or Fellow
 - Full-time Faculty Appointment
 - O Part-time/Adjunct Faculty Appointment
 - Not academically affiliated

7. How long was your residency training? a. ___ years b. ___ months

- 8. How long have you practiced medicine (excluding residency)? a. ___ years b. ___ months
- 9. Specialty Group (check all that apply)
 - a. Family Medicine
 - b. Internal Medicine
 - C. Geriatrics
 - d. Other

d.1 Specify:	

10. During a typical week, approximately how many patients do you see?

- O ≤ 75 O 76-100
- 0 101-125
- O ≥ 126

Thank you for your time



Please read each question carefully and answer it to the best of your ability. There are no correct or incorrect responses; we are merely interested in your point of view. The questionnaire may appear to be monotonous since several of the statements are worded in a repetitive manner. However, the scientific nature of the study requires this methodological approach. Your collaboration is vital to the success of this project. <u>It is important to get your opinion</u>.

Description and Definition: Think about the clinical pharmacist in your medical office. When we use the term **physician\pharmacist collaborative model (PPCM)** for hypertension management we mean an interdependent relationship with the following characteristics. First, you ask the pharmacist to see your patient who is not at BP goal to: 1) assess the patient and their medications, 2) the pharmacist determines the barriers to achieving BP goal, 3) develops a care plan to get to BP goal and recommends that plan to you, 4) if you agree with the plan you give the pharmacist responsibility to implement the plan which may require the pharmacist to provide: a) dosage titrations and medication changes, and b) more frequent office visits with the pharmacist to titrate medications, educate the patient, monitor for side effects, 5) the pharmacist communicates the changes with you, especially for complex issues that require your oversight and collaboration. This process continues until the patient's BP is controlled.

- A. QUESTIONNAIRE
- Think about your last 10 patients whose BP was not controlled (≥140/90 mm Hg if uncomplicated or ≥130/80 mmHg with diabetes). How many patients did you refer to the pharmacist to provide PPCM as defined above? (circle one number).....0 1 2 3 4 5 6 7 8 9 10
- 2. I expect to refer patients with uncontrolled BP to the pharmacist who will then provide PPCM. Strongly disagree 1 2 3 4 5 6 7 Strongly agree
- 3. I want to refer patients with uncontrolled BP to the pharmacist who will then provide PPCM. Strongly disagree 1 2 3 4 5 6 7 Strongly agree
- 4. I intend to refer patients with uncontrolled BP to the pharmacist who will then provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

<u>Scenario 1:</u> One of your patients is visiting you today for the fourth time since her last annual physical she had a year ago. She is a 72 year old, happily married, retired black female. Her H&P is noncontributory except for your diagnosis of hypertension. You have tried several medications and combinations of medications but her BP remains 158/82 mm Hg. As far as you can tell, she is taking her medications as you prescribe.

5. Your decision: Will you refer this lady to your pharmacist for PPCM? O YES O NO

6.	On the scale of	of 1 to 7	7, hov	v diff	icult	will	it be	for	you to refer this patient to the pharmacist?
	Not difficu	lt at all	1	2 3	3 4	5	6	7	Extremely Difficult

7. People who are important to me professionally think that I should refer this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree



8. I am confident that I can refer this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

9. I think that administrators in my clinic/health system that care about quality improvement would approve of me referring this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

10. I think most primary care physicians would approve of me referring this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

11. I feel capable of referring this patient to the pharmacist to provide PPCM.

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

<u>Scenario 2</u>: Another one of your patients with hypertension and diabetes is visiting you today. You see him about once every 3 months for his diabetes which is fairly well controlled. He is 56 years old, overweight and he does not smoke. He has no other problems except osteoarthritis of the knees. Over the past six months his BP has slowly increased from 122/74 to 134/84 mm Hg. He takes maximum doses of lisinopril for his BP and renal protection.

12. Your decision: Will you refer this man to your pharmacist for PPCM? O YES O NO

13. On the scale of 1 to 7, how difficult will it be for you to refer this patient to the pharmacist? Not difficult at all 1 2 3 4 5 6 7 Extremely Difficult

14. For me, referring the patient in Scenario 2 to the pharmacist to provide PPCM would be:

a. Helpful 1 2 3 4 5 6 7 Unhelpful b. Necessary 1 2 3 4 5 6 7 Unnecessary c. Satisfying 1 2 3 4 567 Not satisfying



Consider your working relationship with a pharmacist with whom you work the most. Think, in general, about the interactions you've had with this pharmacist over time (not just for hypertension). Please indicate your agreement with each of the following statements by using the scale listed below. Please circle the number that represents your agreement with the item.

SCALE: 1-Very Strongly Disagree 2-Strongly Disagree 3-Disagree 4-Neutral 5-Agree 6-Strongly Agree 7-Very Strongly Agree

15. In providing patient care, I need this pharmacist as much as this pharmacist needs me.	1	2	3	4	5	6	7
16. The pharmacist is credible.	1	2	3	4	5	6	7
17. My interactions with this pharmacist are characterized by open communication of both parties.	1	2	3	4	5	6	7
18. I can count on this pharmacist to do what he/she says.	1	2	3	4	5	6	7
19. This pharmacist depends on me as much as I depend on him/her.	1	2	3	4	5	6	7
20. This pharmacist and I are mutually dependent on each other in caring for patients.	1	2	3	4	5	6	7
21. This pharmacist and I negotiate to come to agreement on our activities in managing drug therapy.	1	2	3	4	5	6	7
22. I will work with this pharmacist to overcome disagreements on his/her role in managing drug therapy.	1	2	3	4	5	6	7
23. I intend to keep working together with this pharmacist.	1	2	3	4	5	6	7
24. I trust this pharmacist's drug expertise.	1	2	3	4	5	6	7
25. Communication between this pharmacist and myself is two-way.	1	2	3	4	5	6	7

SCALE: 1=Not at all---5=To a great extent

Please indicate the extent to which this pharmacist has

26. Spent time trying to learn how he/she can help you provide better care	1	2	3	4	5	
27. Provided information to you about a specific patient	1	2	3	4	5	
28. Showed an interest in helping you improve your practice	1	2	3	4	5	

23. MANAGING HIGH BLOOD PRESSURE SURVEY (PHYSICIAN) Provider Code: _____ - ___ ___ Page **4** of **4**



- B. PHYSICIAN DEMOGRAPHIC INFORMATION
 - 1. Birth Date: __/_ _/_ __ (mm/dd/yyyy)
 - 2. Gender
 - \bigcirc Male
 - Female
 - 3. Race (check all that apply)
 - □ a. American Indian or Alaska Native
 - □ b. Asian
 - □ c. Native Hawaiian or other Pacific Islander
 - □ d. Black or African-American
 - e. White
 - f. Declined to Answer
 - 4. Ethnicity
 - O Hispanic or Latino
 - Non-Hispanic or Non-Latino Origin
 - O Declined to Answer
 - 5. Spanish Speaker
 - O Yes O No
 - 6. Academic Affiliation
 - O Resident or Fellow
 - Full-time Faculty Appointment
 - O Part-time/Adjunct Faculty Appointment
 - Not academically affiliated

7. How long was your residency training? a. ___ years b. ___ months

- 8. How long have you practiced medicine (excluding residency)? a. ___ years b. ___ months
- 9. Specialty Group (check all that apply)
 - a. Family Medicine
 - □ b. Internal Medicine
 - C. Geriatrics
 - d. Other

d.1 Specify:	

10. During a typical week, approximately how many patients do you see?

- O ≤ 75
- 76-100○ 101-125
- O ≥ 126

Thank you for your time



SUBMIT THIS FORM ELECTRONICALLY WITHIN 24 HOURS OF BECOMING AWARE OF A PROTOCOL DEVIATION

1.	Date of Deviation:	/ /	(mm/dd/yyyy)
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- 2. Date Site became Aware of Deviation: ___ / ___ / ___ / ___ (mm/dd/yyyy)
- Type of Deviation (check all that apply)
 a. Subject did not meet all inclusion criteria
 a.1 Describe unmet criterion or criteria: ____
 - b. Subject met one or more exclusion criteria
 b.1 Describe criterion or criteria:
 - □ c. Subject did not sign informed consent or consent information was not provided to the subject according to IRB-approved procedure
 - □ d. A fourth blood pressure measurement was not taken when the second and third measurements differed by greater than 4 mm Hg.

- e. Subject missed window for 9 month study visit
- ☐ f. Subject missed window for final visit (18 month Asthma or 24 month BP)

g. Serious adverse event was not reported within 24 hours
 g.1 Event Date: ____/ ___ / ____ (mm/dd/yyyy)
 g.2 Describe Event: ______

h. Other

h.1 Specify: _____

Corrective Action Plan (For site use only; do not enter into database.):

Source Document Completed copy must be maintained in subject's study file CORE

Version 2.0 25/Apr/2011 26. BLOOD PRESSURE RE-SCREENING Subject ID: _____- - ____ ___ Page 1 of 1



- 1. Date of re-screening: ___/__/_ (mm/dd/yyyy)
- 2. Blood pressure control
 - Average systolic <130 mm Hg AND average diastolic <80 mm Hg AND subject IS currently diagnosed with diabetes OR chronic kidney disease

Blood pressure is controlled; subject is NOT eligible.

 Average systolic <140 mm Hg AND average diastolic <90 mm Hg AND subject IS NOT currently diagnosed with diabetes OR chronic kidney disease

Blood pressure is controlled; subject is NOT eligible.

 Average systolic blood pressure >200 mm Hg OR average diastolic blood pressure >115 mm Hg

Refer to the Manual of Operations for instructions on handling hypertensive urgencies; subject is NOT eligible.

O Uncontrolled

If one of the following options is selected for Item 2, enter the subject's average research blood pressure in items 2.a and 2.b:

Option 1 – 'Average systolic <130 mm Hg AND average diastolic <80 mm Hg AND subject IS currently diagnosed with diabetes OR chronic kidney disease'

Option 2 – 'Average systolic <140 mm Hg AND average diastolic <90 mm Hg AND subject IS NOT currently diagnosed with diabetes OR chronic kidney disease'

- **Option 3** 'Average systolic blood pressure >200 mm Hg OR average diastolic blood pressure >115 mm Hg'
 - a. Average Systolic: _____
 - b. Average Diastolic: _____

If Item 2 = 'Uncontrolled', complete items 3 and 4 below. If subject's blood pressure continues to be controlled, stop here; do not complete any of the remaining items.

Most recent Short Portable Mental Status Questionnaire (SPMSQ) score: _____

If the SPMSQ score is >2, the subject is NOT eligible.

- 4. Is the subject ineligible for another reason not listed above? (*Review inclusion and exclusion criteria listed in the CAPTION MOP*)
 - O No O Yes
 - a. If yes, specify: _____