PRT Questions from first review of: *Project Sonar* (PS), submitted by the Illinois Gastroenterology Group and SonarMD, LLC

Questions for Submitter

1. Please provide a more in-depth description regarding the intervention. How might Project Sonar be experienced by an individual patient and his or her care team?

Thank you for your question. Project Sonar incorporate the following key actions from a patient engagement standpoint:

- The patient is identified by the payer, based on claims data and disease criteria
- The payer notifies SonarMD and the practice about the patient being a candidate for the program via an attribution list
- The practice engages the patient to discuss the program and schedule the initial intake (Supervisit) and enrollment visits
- The practice communicates to the referring PCP that the patient is enrolled in the SonarMD program
- The patient is provided with information to facilitate communication with the care team, both during and after office hours
- Appropriate consents signed

This diagram below provides an overview of the patient experience.



- 1) Patient Attribution
 - a) The payer attributes the patient with the chronic disease
 - b) The practice engages the patient
 - i) Explains the program
 - ii) Schedules Supervisit with nurse care manager (NCM)
 - iii) May have concurrent provider visit if indicated
- 2) Patient Enrollment
 - a) The patient undergoes an enrollment visit which includes:
 - i) Identification of Goals, Barriers
 - ii) Depression Screen
 - iii) Nutritional Assessment
 - iv) Action Plan
 - v) Consent Forms
 - vi) Signoff by all
 - b) Enrollment in SonarMD Platform
 - i) Initial Manual Ping
 - ii) Initial Sonar Score
- 3) Patient Hovering
 - a) Patient receives a "ping" text message with secure hyperlink on first business day of each month
 - i) If patient does not respond, a second ping is sent out one week later
 - ii) If patient still does not respond, they are contacted by phone
 - iii) Patient completes disease specific questionnaire
 - b) Sonar Score is calculated by platform
 - c) Immediate feedback is provided to the patient
 - d) Sonar Score is sent to NCM

- e) NCM interprets score based upon algorithm
- f) NCM communicates with provider if necessary
- 4) Data Analysis
 - a) Payer provides quarterly claims data to SonarMD
 - b) SonarMD provides performance reports to practice
 - i) Sonar Ping response rate
 - ii) Average Sonar Score by practice, provider and NCM
 - iii) Average Sonar Slope by practice, provider and NCM
 - iv) Cost Analysis
 - (1) OPT Medical Cost
 - (2) INPT Medical Cost
 - (3) Emergency Room Expense
 - (4) Biologic Expense

2. Are patients generally only "touched" once per month with a survey? Is there any follow-up for "non-pingers"?

Patients are touched a <u>minimum</u> of once per month. Those whose score indicates a problem are 'touched' more often, whether in-person, via phone, or survey. Although the initial "touch" is via the web-based survey, all patients are contacted. Overall, we have a sustained 80% response rate to the SonarMD software. Non-responders are contacted by phone.

The process is as follows:

- The Ping is sent on the first business day of the month at 10AM in the time zone of the patient
- Patients are listed as "nonresponder" on the SonarMD desktop and monitored by the NCMs until they respond
- If the patient has not responded in one week, a second ping is automatically sent on day seven (7).
- Patients who have not responded to the second ping are now updated in the Nonresponder tab for the NCM to contact
- The NCM calls the patient via telephone, which is repeated every 1-2 days until the patient is contacted. Answers to the questionnaire are obtained via phone and manually entered by the NCM into the SonarMD system

3. Project Sonar has been tested with the commercially insured population, which is different (e.g. age distribution) than the Medicare population. Is there evidence that Project Sonar can engage patients and is successful across different patient demographics, including the Medicare population?

Yes, there is evidence that Project Sonar can engage patients across different demographics, including the Medicare population. The 21 Gastroenterology (GI) practices have enrolled Inflammatory Bowel Disease patients on the platform regardless of the payor or age of the patient. Over 20% of the patients enrolled to date are Medicare.

4. Please further clarify how the Sonar Score is calculated and the thresholds that determine a need for further intervention.

The Sonar Score for IBD is calculated from a subset of questions derived from the Crohn's Disease Activity Index, a well-established index of disease activity for IBD¹. The subset of questions selected are those that a patient can answer on their own without the assistance or presence of a health professional, as shown below:

¹ Best WR, Becktel JM, Singleton JW, Kern F; Development of a Crohn's disease activity index. Gastroenterology 1976; 70: 439-44.

IGG CD CDAI Calculator
Sonar Score 04/14/2014
For the last seven days please describe each of the following:
Number of loose stools per day: C 0 C 1 C 2 C 3 C 4 C 5+
Abdominal pain or cramps: O None O Mild O Moderat O Severe
General Well Being: C Generally Well C Slightly Under C Poor C Very Poor C Terrible
Select all the symptoms you have had below:
🗖 Arthritis or Joint Pain 🛛 Eye Pain 🔲 Painful Skin Rash or Bumps 🔲 Fever over 100 Degrees
Are you on any drugs for diarrhea
Total Calculate
OK Cancel

The Sonar Score is calculated as the sum of the values on each of the questions. Their relative score ratings are shown in the table below:

Sonar Score	
Question	Metric
Number of loose stools per day	0,1,2,3,4,5
Abdominal Pain or Cramps	0,5,10,15
General Well Being	0,7,14,21,28
Individual Items	
Arthritis or Joint Pain	0,20
Eye Pain	0,20
Painful Skin Rash or Bumps	0,20
Fever over 100 degrees	0,20
Use of drugs for diarrhea	0,30
Sonar Score	Sum of all

The score is deemed worthy of a response by the NCM if the raw score is over 40. When this occurs, the patient and score turns red on the NCM desktop.

In addition to raw scores, the slope of the scores over the last three sessions is calculated. If this exceeds 20, the score turns red as well. This allows the physician and NCM to avoid missing trends in patients whose raw scores might be below the raw score threshold.

5. With commercial payors, Project Sonar has focused on Crohn's Disease. Are you proposing a model that includes only Crohn's Disease or are you proposing a model that expands to other chronic illnesses?

We are proposing a model that expands to address conditions in addition to Crohn's Disease. We believe that the patient characteristics in the CD population which we have uncovered can be advanced and expanded to other high beta chronic diseases. We define high beta diseases as those that are high cost per patient with high variability in cost per year and high potential to avoid unnecessary Emergency Department (ED) and inpatient (IP) admissions. Ulcerative Colitis and Irritable Bowel Syndrome have already been placed in production. Development is in place for End Stage Liver Disease, COPD and periods in Diabetes. Other examples of high beta conditions include chronic inflammatory diseases such as rheumatoid arthritis and systemic lupus erythematosus, heart failure, renal failure and other conditions.

6. To what degree will there be coordination with primary care providers?

Coordination with the patient's primary care providers (PCPs) is critical. The platform is designed to feed information to any of the providers involved in the care of the patient. Critical to the management of the patient is a recognition of and establishing whom is the responsible provider, and how the patient is co-managed by the PCP and specialist. This is determined during the Supervisit and initial enrollment, and reinforced by the NCM on a regular basis.

7. Can you provide the biopsychosocial risk assessment tool?

The biopsychosocial risk assessment tool shown below has been developed based on multiple sources including the American Gastroenterological Association's Crohn's Disease Care Pathway. The risk assessment tool addresses three categories of risk: Disease Burden, Inflammation Burden and Comorbidity Burden. It is shown in in the figure on the next page.

Step 1

Step 2

<mark>Step 1</mark> Disease Burden Ris	k Assessm	ent	Step 2 Inflammation Burden F	Risk Assessment	Step 3 Comorbidity Burden Risk Assessment
	Low Risk	High Risk	Symptoms	Lab Abnormalities	Comorbidity
Age at Diagnosis:	Over 30	O Under 30	Fever Abdominal Rain	Low Hb	Examples: C Ditt, CMV
Anatomic Involvement:	O Limited	Extensive	Abdominal Pain		Stricturing/Remodeling
Perianal Disease:	O No	O Yes	GI Bleeding	Elevated CRP Decreased Albumin	Examples: Abnormal Imaging, Obstructive Symptoms Weight Loss
Severe Rectal Disease:	O No	O Yes	Weight Loss	Elevated ESR	Symptoms from Prior Surgery Examples: Bile Acid Diarrhea, Bacterial Overgrowth,
Deep Ulcers:	O No	O Yes	Joint Pains	Elevated FCP	Steatorrhea
Stricturing:	O No	O Yes	Cutaneous Signs		Adverse Medical Reaction Examples: Recent addition of new drug: drug holiday
Penetrating Disease:	O No	O Yes	Overall Risk:	High	Abnormal Abscess/Fistula Examples: Pain, Fistula, Drainage, Fever
Overall Risk:	Low				Perianal Abscess/Fistula Examples: Pain, Fistula, Drainage, Fever

The biological risk assessment is combined with a depression risk using the PHQ-2:

Depression Screen PHQ-2						
During the past two weeks, how often have you been bothered by any of the following problems:	Not at all	Several Davs	More than half the days	Nearly Every Day		
 Feeling little interest or pleasure in doing things: 	0	c	C	0		
2) Feeling down, depressed or hopeless:	0	0	C	0		
Action Plan Calculate 3	A score of	f 3 indicate: depre	s a 90% likeli ssion	hood of		

We are piloting the implementation of the Hospital Anxiety and Depression Score (HADS) and the CDC Healthy Days Core Measures.

8. Please explain your risk adjustment methodology more fully. Also explain how it relates to shared savings/losses.

The risk adjustment is based upon clinical characteristics and how each one influences the cost of care. The following metrics are used in our risk assessment:

- Age
- Sex •
- Disease Phenotype as determined by ICD-10 Code •
- PHQ-2 rating •
- The 26 individual metrics from the AGA Crohn's Disease Care Pathway
- Sonar Ping response rate •

For each item, a relative value derived from the performance of multiple linear regressions of the item against the Crohn's related cost of care is then factored in. The following illustrates this calculation methodology. We anticipate further refinement with larger populations.

			Uncorrected		
Variable	Sum	Mean	SS	Variance	Std Dev
Intercept	83	1	83	0	0
age	3613	43.53012	171889	178.22774	13.3502
ageatdx	865	10.42169	19419	126.88099	11.26415
male	33	0.39759	33	0.24243	0.49238
yrs_sincedx	2748	33.10843	107224	198.07346	14.07386
corisk_abcess	4	0.04819	4	0.04643	0.21548
corisk_advrx	2	0.0241	2	0.0238	0.15428
corisk_assessed	105	1.26506	177	0.53864	0.73392
corisk_inf	3	0.03614	3	0.03526	0.18778
corisk_metricbased	37	0.44578	85	0.83544	0.91402
corisk_perianal	6	0.07229	6	0.06788	0.26054
corisk_priorsg	8	0.09639	8	0.08816	0.29691
corisk_stricturing	14	0.16867	14	0.14193	0.37674
dzburden_anatomic	26	0.31325	26	0.21775	0.46664
dzburden_penetratingdz	12	0.14458	12	0.12518	0.35381
dzburden_perianal	12	0.14458	12	0.12518	0.35381
dzburden_rectaldz	6	0.07229	6	0.06788	0.26054
dzburden_stricturing	15	0.18072	15	0.14987	0.38713
dzburden_ulcers	13	0.15663	13	0.13371	0.36566
inflrisk_abdominalpain	32	0.38554	32	0.23979	0.48968
inflrisk_albumin	5	0.06024	5	0.0573	0.23938
inflrisk_crp	12	0.14458	12	0.12518	0.35381
inflrisk_cutaneous	2	0.0241	2	0.0238	0.15428
inflrisk_esr	3	0.03614	3	0.03526	0.18778
inflrisk_fcp	0	0	0	0	0
inflrisk_fever	1	0.01205	1	0.01205	0.10976
inflrisk_gibleed	7	0.08434	7	0.07817	0.27958

Descriptive Statistics

Use of this methodology is complimentary to assessment of the patient using Hierarchical Condition Categories (HCC) and related tools.

Providers are rated on 1) patient participation / engagement 2), their patient's risk adjusted average sonar scores, and 3) medical, facility, hospital, pharmaceutical and total costs of care for their patients compared to the medical group, geographic (MSA) and national data. Performance is measured on a quarterly basis, and is reflected in distribution of shared savings on a quarterly and yearly basis.

9. How is the target price determined? Is target price based on the total cost of care or is it specific to Crohn's Disease spending?

We have calculated the target cost in both ways. At present, our data suggests use of the Crohn's specific target. We have identified ICD-10 codes that are specific to Crohn's disease as well as other ICD-10 codes for Crohn's related conditions, which is factored into calculation of the target price.

10. Will the target price be adjusted over time? If so, what is the frequency and method of adjustment?

We anticipate that the target price will be adjusted over time, based on continual comparison of the study group against a control group.

Data from Health Care Service Corporation / BCBS IL was made available after the PFPM proposal was submitted. The results differ from the data presented in the PTAC proposal as they reflect completed claims 90 days post service and compare the study group against an age/sex/risk matched control group.

	Trending Pre to Post			
Metrics	Ping	Matched Ping	Non Ping	Matched Non Ping
Age & Gender Factor	2.8%	3.1%	2.0%	4.1%
Admissions Per 1000	0.0%	100.0%	57.1%	137.5%
Days Per 1000	0.0%	172.0%	96.2%	102.7%
ALOS	0.0%	36.0%	24.8%	-14.7%
Admission Allowed PMPM	-11.5%	186.4%	123.1%	176.7%
ER Allowed PMPM	-2.8%	93.0%	-8.1%	69.4%
Outpatient Allowed PMPM	1.2%	49.7%	13.2%	30.9%
Total Medical Allowed PMPM	14.2%	44.5%	31.9%	41.4%
Total Medical Allowed PMPM (Excluded Infused Bio)	-1.3%	69.8%	31.3%	50.8%

The results are very favorable and show:

- There were no Crohn's admissions in the study group among the actively responding (pinging) patients.
- Total Medical Allowed cost minus biologics FELL by 1.3% in the pinger study group whereas it rose by 69.8% in the matched control group.

These types of analyses will be required to calculate target prices for a bidirectional risk model, recognizing that the target prices may fluctuate over time based on costs that are not under our control (e.g. Medicare physician, outpatient prospective payment, and clinical laboratory fee schedules, pharmaceutical average sales price calculations, etc.).

11. Provide additional detail on how Project Sonar will improve or maintain quality. Will any other patient reported outcomes (besides PHQ 2) be included?

Our goal is to continuously use the science behind the risk assessment to determine the most valuable quality metrics going forward. Our research has identified that serum albumin in CD patients is the most powerful driver of variation in cost. Ping response rate is a predictable driver of cost and can be used as a major metric of quality. We recognize the limitations of the PHQ-2 and are testing implementing the HADS and CDC Healthy Days.

12. Can you provide an overall estimate of savings to Medicare for different levels of enrollment?

Our savings are calculated and normalized based on Medicare rates. We believe that the cost savings achieved through reduction in ED visits and IP admissions, along with improved medication adherence, better care coordination, and moving infusion services from hospital outpatient to non-facility office settings appropriately reflect the savings that would be achieved in Medicare beneficiaries.

13. Is the technology described in this proposal proprietary? If so, is it your plan that it remain proprietary?

The SonarMD platform is currently proprietary. The platform questions could be replicated by others and could be incorporated into an EHR. However, the true proprietary value of Project Sonar lies not with the IT platform, but in the chronic care management algorithms, the clinical decision support (hovering) tools, and the predictive analytics which will guide patient engagement based on the metrics that we collect.

PRT questions on: Project Sonar (PS), submitted by the Illinois Gastroenterology Group and SonarMD, LLC

Questions for Submitter

1. Over 20% of the patients enrolled in Project Sonar to date are Medicare beneficiaries. How many patients are enrolled in Project Sonar to date (what is the denominator)? Is Medicare currently participating in Project Sonar in some way (e.g. a pilot) or are the Medicare beneficiaries enrolled in Project Sonar in Medicare Advantage or beneficiaries for whom Medicare is a secondary payor?

Subsequent to submission of the proposal to PTAC in December 2016, enrolled patients have continued to increase. The majority of new enrollees are commercial, as BCBS IL has expanded this program throughout Illinois effective January 1, 2017. As of February 3, 2017, there are 674 patients in the SonarMD Database, 50 of whom are Medicare beneficiaries. At present, beneficiaries in original Medicare or Medicare Advantage are not participating in Project Sonar *as a pilot*.

2. Please clarify what is meant by "patient engagement." Is it the same as ping response rate?

Patient Engagement means that each patient is communicated with on at least a monthly basis, and a survey completed. The ping response rate refers to the use of the digital platform for this function and hovers around 78% overall. The remaining 20% of patients are engaged via phone or in person at the time of an encounter such as an infusion, procedure or office visit.

3. Is the level of patient engagement and distribution of pingers versus nonpingers for Medicare beneficiaries similar to other patients enrolled in Project Sonar?

The ping response rate for patients over 65 is 65.44%, compared to 78% in commercial patients. Attempts to engage patients are performed on an at least monthly basis. If the patient is unable or unwilling to use the SonarMD online platform, the patient is contacted via telephone.

4. How will information be transmitted to the primary care physician? What kind of information will be shared with the primary care physician?

At present, the primary care physician (PCP) receives faxed notes when there is an intervention. These notes address changes in patient status and the resulting management decisions. As the SonarMD platform is web-based, there is no reason that a PCPs could not access the exact same data that the specialist accesses. As the Sonar Scores are pushed into the EMR as lab data, these can easily be pushed to the PCP.

5. What are the incentives for primary care physicians' involvement? Are primary care physicians eligible for shared savings or at risk for shared losses?

In the pilot with BCBS IL, the structure did not incorporate PCP financial involvement. Project Sonar was based on the concept of a specialist assuming responsibility for the management of the patient with a complex condition that could or would not be managed by the PCP. Thus, as PCP are involved in a manner similar to the typical PCP/specialist communication. It was determined that, at present, they would not be financially eligible for shared savings or at risk for shared losses. As Project Sonar collects data on patients and physicians, we envision having sufficient data in subsequent years that would allow all healthcare professionals participating at the group level to see their performance, that this data could be shared with the referring PCPs, and that PCPs could use the performance data to specify which specialist to refer the patient to. If the specialist is clinically and financially integrated with a PCP group, that model would lend itself to the specialist and PCP being eligible for shared savings and at risk for shared losses.

6. Is it your intent that the IT platform, chronic care management algorithms, clinical decision support tools, and predictive analytics remain proprietary?

As noted in our previous responses, at present the SonarMD platform is proprietary. That being said, the platform could be replicated by others and does not need to remain proprietary. However, the true value of Project Sonar is in the chronic care management algorithms, the clinical decision support (hovering) tools, and the predictive analytics which guide patient management based on the metrics and data collected. As these have intellectual property value, they will remain proprietary.

7. In response to our initial set of questions, you indicate that you have calculated target cost in two ways: (1) based on total cost of care and (2) based on costs specific to Crohn's Disease. Please clarify whether the data in your proposal and the Health Care Service Corporation / BCBS IL data in your response are based on total cost of care or Crohn's-related cost of care.

The HCSC/BCBS IL data, which was submitted previously to the PTAC and copied below, reflects the Total Cost of Care.

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8. The proposal outlines an upside risk revenue share model. How are shared losses distributed?

To date, we have not had incurred any shared losses. If the total cost of care exceeds the target amount, losses would be distributed to the specialist medical group operating under a TIN. There are two models for distributing shared losses. At the Illinois Gastroenterology Group, the model requires the losses to be shared equally amongst the physicians in the group. We see this evolving into a model where the specialist group would determine which physicians / healthcare professionals were responsible for the management of the patients. The group as a whole would share some portion of the losses, and the individual physicians managing the patient would have responsibility for their percentage of the losses.

9. In response to our initial set of questions, you indicate that you have identified ICD-10 codes specific to Crohn's disease and for Crohn's related conditions. What related conditions are included?

The following list of diagnoses was used in our initial analysis. At the time, our study period involved a period which included the use of ICD-9 and ICD-10. The conditions listed below were determined by our physician panel to be potentially referable to Crohn's Disease based upon symptoms or complications. In the interests of responding rapidly to the PTAC's questions, we have not provided the ICD-10 codes. If provision of ICD-10 codes is required, we will provide such in a subsequent communication

Gastrointestinal symptoms referable to Crohn's

Symptoms concerning nutrition metabolism and development Anorexia Abnormal weight gain Abnormal loss of weight and underweight Loss of weight Underweight Symptoms involving digestive system Nausea and vomiting **Bilious** emesis Heartburn Dysphagia Dysphagia, oral phase Dysphagia, oropharyngeal phase Dysphagia, pharyngeal phase Dysphagia, pharyngoesophageal phase Other dysphagia Visible peristalsis

Abnormal bowel sounds Incontinence of feces Full incontinence of feces Incomplete defecation Fecal smearing Fecal urgency Abnormal feces Other symptoms involving digestive system Other symptoms involving abdomen and pelvis Abdominal pain Abdominal pain, left upper quadrant Abdominal pain, periumbilic Abdominal pain, epigastric Abdominal or pelvic swelling mass or lump Abdominal or pelvic swelling, mass, or lump, left upper quadrant Abdominal or pelvic swelling, mass, or lump, left lower quadrant Abdominal or pelvic swelling, mass, or lump, epigastric Abdominal or pelvic swelling, mass, or lump, generalized Abdominal or pelvic swelling, mass, or lump, other specified site Abdominal rigidity Abdominal rigidity, unspecified site Abdominal rigidity, right upper quadrant Abdominal rigidity, left upper quadrant Abdominal rigidity, right lower quadrant Abdominal rigidity, left lower quadrant Abdominal rigidity, periumbilic Abdominal rigidity, epigastric Abdominal rigidity, generalized Abdominal rigidity, other specified site Abdominal tenderness Abdominal tenderness, unspecified site Abdominal tenderness, right upper quadrant Abdominal tenderness, left upper quadrant Abdominal tenderness, right lower quadrant Abdominal tenderness, left lower quadrant Abdominal tenderness, periumbilic Abdominal tenderness, epigastric Abdominal tenderness, generalized Abdominal tenderness, other specified site Colic Other symptoms involving abdomen and pelvis

Other Lower Digestive System Conditions

- Intestinal obstruction without mention of hernia
- Intussusception
- Volvulus
- Impaction of intestine
- Impaction of intestine, unspecified
- Gallstone ileus
- **Fecal impaction**
- Other impaction of intestine
- Other specified intestinal obstruction
- Diverticula of intestine
- Diverticula of small intestine
- Diverticulosis of small intestine (without mention of hemorrhage)
- Diverticulitis of small intestine (without mention of hemorrhage)
- Diverticulosis of small intestine with hemorrhage
- Diverticulitis of small intestine with hemorrhage
- Diverticula of colon
- Diverticulitis of colon (without mention of hemorrhage)
- Diverticulosis of colon with hemorrhage
- Diverticulitis of colon with hemorrhage
- Other postoperative functional disorders
- Functional diarrhea
- Anal spasm
- Megacolon, other than Hirschsprung's
- Other specified functional disorders of intestine
- Neurogenic bowel
- Unspecified functional disorder of intestine
- Peritonitis and retroperitoneal infections
- Peritonitis in infectious diseases classified elsewhere
- Pneumococcal peritonitis
- Other suppurative peritonitis
- Peritonitis (acute) generalized
- Spontaneous bacterial peritonitis
- Other suppurative peritonitis
- **Retroperitoneal infections**
- Psoas muscle abscess
- Other retroperitoneal abscess
- Other retroperitoneal infections
- Other specified peritonitis
- Choleperitonitis
- Other specified peritonitis
- Unspecified peritonitis
- Other disorders of intestine

- Rectal prolapse
- Stenosis of rectum and anus
- Hemorrhage of rectum and anus
- Other specified disorders of rectum and anus
- Ulcer of anus and rectum
- Anal sphincter tear (healed) (old)
- Dysplasia of anus
- Abscess of intestine
- Colostomy and enterostomy complications
- Colostomy and enterostomy complication, unspecified
- Infection of colostomy or enterostomy
- Mechanical complication of colostomy and enterostomy
- Complications of intestinal pouch
- Pouchitis
- Other complications of intestinal pouch
- Other specified disorders of intestine
- Perforation of intestine
- Angiodysplasia of intestine (without mention of hemorrhage)
- Angiodysplasia of intestine with hemorrhage
- Dieulafoy lesion (hemorrhagic) of intestine convert
- Vomiting of fecal matter

Upper Digestive System (Esophagus Stomach and Duodenum) Conditions

Diseases of esophagus Achalasia and cardiospasm Esophagitis Esophagitis, unspecified Acute esophagitis Eosinophilic esophagitis Other esophagitis Ulcer of esophagus Ulcer of esophagus without bleeding Ulcer of esophagus with bleeding Stricture and stenosis of esophagus Perforation of esophagus Dyskinesia of esophagus Diverticulum of esophagus, acquired Gastroesophageal laceration-hemorrhage syndrome Other specified disorders of esophagus Esophageal hemorrhage

- Esophageal leukoplakia
- Tracheoesophageal fistula

Barrett's esophagus

- Infection of esophagostomy
- Other specified disorders of esophagus
- Unspecified disorder of esophagus
- Gastritis and duodenitis
- Acute gastritis
- Acute gastritis, without mention of hemorrhage
- Acute gastritis, with hemorrhage
- Atrophic gastritis
- Atrophic gastritis, with hemorrhage
- Gastric mucosal hypertrophy
- Gastric mucosal hypertrophy, without mention of hemorrhage
- Gastric mucosal hypertrophy, with hemorrhage
- Other specified gastritis
- Other specified gastritis, with hemorrhage
- Unspecified gastritis and gastroduodenitis
- Unspecified gastritis and gastroduodenitis, with hemorrhage
- Duodenitis
- Duodenitis, with hemorrhage
- Eosinophilic gastritis
- Eosinophilic gastritis, without mention of hemorrhage
- Eosinophilic gastritis, with hemorrhage
- Other disorders of stomach and duodenum
- Acquired hypertrophic pyloric stenosis
- Gastric diverticulum
- Chronic duodenal ileus
- Gastroptosis
- Hourglass stricture or stenosis of stomach
- Other specified disorders of stomach and duodenum
- Pylorospasm
- Angiodysplasia of stomach and duodenum without mention of hemorrhage
- Angiodysplasia of stomach and duodenum with hemorrhage
- Dieulafoy lesion (hemorrhagic) of stomach and duodenum
- Other specified disorders of stomach and duodenum
- Unspecified disorder of stomach and duodenum

Malnutrition Related

- Other severe protein-calorie malnutrition
- Malnutrition of Mild Degree
- Arrested development following protein-calorie malnutrition
- Other protein-calorie malnutrition

Vitamin A deficiency Vitamin B deficiency Vitamin C deficiency Vitamin D deficiency Unspecified nutritional deficiency

Anemia

Iron deficiency anemias Iron deficiency anemia secondary to inadequate dietary iron intake Other specified iron deficiency anemias

Other deficiency anemias Folate-deficiency anemia Other specified megaloblastic anemias not elsewhere classified Protein-deficiency anemia Anemia associated with other specified nutritional deficiency Unspecified deficiency anemia

Miscellaneous Conditions related to Crohn's disease

- Osteoporosis
- Osteopenia
- Erythema Nodosum
- Pyoderma, unspecified
- Pyoderma gangrenosum
- Other pyoderma
- Acute and subacute iridocyclitis
- Acute and subacute iridocyclitis, unspecified
- Primary iridocyclitis
- Recurrent iridocyclitis
- Secondary iridocyclitis, noninfectious
- Chronic iridocyclitis
- Chronic iridocyclitis, unspecified
- Chronic iridocyclitis in diseases classified elsewhere
- Certain types of iridocyclitis
- Scleritis and episcleritis
- Episcleritis periodica fugax
- Nodular episcleritis
- Other scleritis and episcleritis

10. In the proposal, you indicate that you normalized commercial data to Medicare payments and saw a 9.87% net savings equal to \$1,000 savings per patient per year. Do you anticipate that level of savings to Medicare regardless of levels of enrollment?

Our net savings was driven by declines in inpatient hospital admissions and Emergency Room visits, despite an increase in pharmaceutical costs due to improved adherence. This data was not adjusted for patient risk or co-morbidities. We anticipate the same level of savings could be realized by Medicare beneficiaries, adjusted for patient risk and co-morbidities. We caution that certain costs, such as part B or part D drugs, the OPPS fee schedule, or advancements in clinical and/or diagnostic evaluation and management, are not in our control and could impact the level of savings to Medicare in future years.

11. In the proposal you indicate that quality reporting will be based upon mutually agreed upon measures, including MIPS and Project Sonar derived measures. The upside risk revenue share model is based on (1) number of patients followed, (2) ping response rate, and (3) risk adjusted cost of care. By how much will quality be improved? Do you have specific benchmarks or targets?

We define value as follows:



Population Outcome +Population Service

Population Cost

Population Outcome can be further defined as equivalent to quality. Our objectives of outcome include:

- Decline in Hospitalization Rate and its maintenance. We lowered this by 53%. We do not have a hospital admission in our Pinger Group.
- Decline in Emergency Room Utilization and its maintenance. We lowered this by 57%
- Decline in lost time from work. While this needs to be assessed, we recognize that this is a soft cost which is not applicable to the Medicare program.

The metrics needed to accomplish these outcomes are driven by the analytics behind cost and risk assessment. As stated in our proposal and in our response to question 8 from the initial (previous) set of questions from the PTAC, we have analyzed the relationship between our risk assessments and the Crohn's-related cost of care. Multiple linear regressions have been used to create a relative strength of our risk metrics, which is incorporated into the algorithms used for patient management. The relative value of the metrics drives management decisions over time. The most significant example is the use of serum albumin, which we found to be the most powerful driver of the variation in cost. Learning from the data generated and analyzed, we obtain serum albumin levels on a quarterly basis on Crohn's Disease patients managed under Project Sonar. Our data has revealed a rising albumin slope in pinging patients and a falling

slope in non-pinging patients. We are looking at other metrics such as fecal Calprotectin and serum C-Reactive Protein to determine whether these are predictive biomarkers which can be used by the physician and beneficiary to proactively identify those patients at risk and to intervene early in order to avoid complications and otherwise potentially preventable ED visits and inpatient admissions. We will continue to analyze the data and refine our predictive tools over time. This same exercise can be used in other chronic conditions.

Project Sonar response to the PRT

Introduction

Good afternoon members of the Physician Focused Payment Model Technical Advisory Committee. I'd like to first thank you all for allowing us the opportunity to address the comments and conclusions of the Preliminary Review Team (PRT). It's obvious from the report of this team that the three reviewers spent a significant amount of time reviewing the details of our proposal for Project Sonar(PS) but were in need of additional information. We welcome this opportunity to provide further information on PS which will hopefully allow the full committee to see the value propositions of our proposal:

- Proactive engagement of the patient leading to better outcome of care
- Tighter patient adherence to medications
- Avoidance of unnecessary care
- Lower ER and Inpatient utilization
- Lower overall cost

On this basis, it is our hope that the full PTAC will approve PS for at least limited-scale testing of the proposed payment mode.

A small degree of background information will assist our discussion. Project Sonar has been a passion of mine for the last five years, originating from a 2012 initiative I undertook as chairman of the Practice Management and Economics Committee of the American Gastroenterological Association designed to find a way to move Gastroenterologists from a dependency on procedural services towards one that would promote Value Based Care. Inflammatory Bowel Disease (Crohn's Disease and Ulcerative Colitis) is the most significant chronic disease state managed by Gastroenterologists and as such was most appropriate for us to study. As stated in our proposal, I began with a review of two years of commercial claims data on 21,000 patients with Crohn's Disease provided to us by BCBSIL. It revealed that over 50% of the expenditures incurred were for inpatient care for the treatment of complications of CD. Most importantly, over 2/3 of the patients who were admitted to a hospital for a complication related to CD had no evidence of a CPT Code for an encounter with any provider in the 30 days prior to the admission. This last item was most concerning to us. Interviews with a representative sample of these patients revealed a common set of responses:

- I thought I had the flu
- I figured it would get better
- I didn't want to bother you
- I have so many other things going on in my life

Clearly these patients with a known serious chronic disease were "going over the cliff" without realizing it and therefore would benefit from tighter patient engagement.

I always open my presentations on Sonar with a picture of the ocean. My patients with IBD are submarines. They are out there running silent and running deep, only surfacing when they have problems, which means two things have to happen. They have to recognize they are deteriorating and realize that they cannot fix it themselves. They make mistakes in both of these. In addition, if you ask them how they are doing, they will tell you they are "fine". It is only with structured patient reported

outcome measures that you can assess true control. We decided to create a patient hovering system, a Sonar System, that would ping patients in between their face to face visits and return structured data back to their healthcare professional team. This was the nidus for Project Sonar, which led in 2014 to the formation of the first Intensive Medical Home Blue Cross Blue Shield Illinois had ever entered with a Specialty Group.

PS has now been in operation for over two years in the Illinois Gastroenterology Group (IGG) and has resulted in over a \$6,000 per year annual savings for BCBSIL on a disease process that averages \$24,000 annually. That's a 25% savings. (see attached article from HFMA)

On the basis of the success in the IGG, BCBSIL engaged SonarMD late last year to implement PS into all Gastroenterology practices in Illinois. We have begun this process and have added five other Illinois Practices to date. It would be our goal to bring this to the Medicare and Medicaid population.

Our success has also resulted in the creation of similar IMH programs for IBD in Minnesota and New Jersey. In other states where no IMH program exists, we have an additional 20 large GI practices involving over 600 physicians across the country that are using the Sonar platform and are enrolling patients even though they do not as yet have IMH programs in their states. This reflects the hunger among most physicians to be part of the value-based transition. In these practices we have provided the platform free of any ongoing license fees.

PRT Review

The PRT comments fall into three main categories:

- 1) Limited Scope
- 2) Lack of adequate quality measures that drive changes in reimbursement
- 3) Lack of need for change in payment methodology

I'd like to address each of these at this time

Limited Scope

Criterion 1: Scope of Proposed PFPM (High Priority Criterion). The proposal aims to broaden or expand the CMS APM portfolio by either: (1) addressing an issue in payment policy in a new way, or (2) including APM Entities whose opportunities to participate in APMs have been limited.

Details are limited to the submitters' experience with IBD, specifically Crohn's Disease which involves only 0.48% of the Medicare fee-for-service population. Medicare beneficiaries with IBD accounted for just 1.25% of Medicare fee-for-service spending.

We agree with the PRT that CD represents only 0.48% of the Medicare FFS population. Unfortunately, its costs are 2.5 times higher than that percentage as these are high cost/high risk patients. Ulcerative Colitis(UC) was not included in our PTAC proposal but has been implemented into our platform. UC is more prevalent than CD especially in the Medicare population and has similar cost. The addition of UC brings our total IBD population to near 0.8% of the total population. The incidence of IBD is rising and it

is estimated that it will reach 2.2M Americans by 2025. Multiplying this by the 250% factor for cost and IBD should be responsible for 2.5% of the total Medicare Fee for Service Spending.

Although our study population was originally limited to Inflammatory Bowel Disease, we are confident that the patient reactions that have been the driving force behind our new care model are not specific to IBD but rather are typical of most patients who deal with chronic disease on a regular basis.

Accordingly, we have moved beyond IBD and are now engaged in multiple non-IBD projects. We have implemented a version of our platform for Irritable Bowel Syndrome which is responsible for 15% of all patient visits in Gastroenterology. Another high cost, high variability condition that would benefit from improved coordinated care is Cirrhosis complicated by Hepatic Encephalopathy (HE):

- a. 37% of patients discharged with a diagnosis of Cirrhosis have a readmission within 30 days
- b. 46,000 patients in the four categories of CMS core measures (AMI, HF, COPD, PN) have a comorbidity of Cirrhosis

Accordingly, we have initiated a study using the SonarMD platform for patients with ESLD focusing on the immediate 30 day post HE hospitalization period where patients and their designated surrogate will be pinged on a daily basis.

We have ventured outside the GI space with two projects:

- 2) COPD:
 - a. 4.7M patients in US with COPD
 - A review of readmission statistics from a Chicago Academic Medical Center reveals a 48% 30-day readmission rate with 1.6 readmissions per episode

Using a similar 30 day post hospitalization period with daily pinging we have initiated a study with this academic medical center for COPD

- 3) Type II DM
 - a. Under the recommendation of BCBSIL we have initiated a project focusing on periods of high HbA1c levels which are associated with high intensity of services
 - b. This project will be deployed into Primary Care Groups in our service area.

PS is not specific to specialty practices but is equally as applicable to Primary Care Practices.

Furthermore, while 20 large gastroenterology (GI) practices have implemented the SonarMD platform, practice feasibility, level of interest, and potential impact based on practice size and specialty are not included.

SonarMD has been deployed across the country into 20 Gastroenterology Practices of sizes that vary from solo practitioners to large GI Mega Groups of over 50 physicians. We have provided the software platform free of any license fee requiring only a small implementation fee. This economical implementation is the result of the fact that the platform is web-based, centrally managed and easily accessible with an Internet connection. The implementation of the clinical platform requires the use of RNs or MAs who can interact with the web-based desktop and integrate with the physician staff.

Although our practices to date have been GI, there is no reason why this same platform cannot be implemented in any practice type, Primary Care Physician or Specialist.

Lack of adequate quality measures that drive changes in reimbursement

Criterion 2. Quality and Cost (High Priority Criterion). The proposal is anticipated to (1) improve health care quality at no additional cost, (2) maintain health care quality while decreasing cost, or (3) both improve health care quality and decrease cost.

The PRT is concerned that the model lacks comprehensive and robust quality measures. The examples for IBD seemed fairly limited, and specific performance targets were not mentioned specifically: metrics tied to reductions in cost, overall improvement in care, and patient satisfaction.

Several proposed quality reporting measures are based upon laboratory values which are important but again are not necessarily unique or novel, nor do they align to the payment proposed. For example, while the proposal notes the value of serum albumin levels in risk categorization, its value as a quality measure does not seem impactful given that there is not necessarily a link to payment for albumin levels, nor is it clear if that is an appropriate direction for the payment model. It is also unclear what the current status of these potential measures is in regards to development, evaluation, endorsement, and implementation. Therefore, the PRT is not convinced that the proposal would improve health care quality at no additional cost, maintain quality while decreasing cost, or both improve quality and decrease cost.

There is significant "clicking fatigue" among all providers resulting from a paucity of "meaningful metrics" clearly associated with direct changes in patient outcome. Most metrics available today are process measures that are not directly associated with clinical outcomes. We have strived to scientifically identify quantifiable metrics that are clearly associated with favorable outcomes. Our albumin example mentioned in our PTAC proposal was just one example of this endeavor. To arrive at this metric we performed an analysis of each of our 26 risk assessment metrics comparing their specific effect on cost using multiple linear regressions. Serum albumin may not be a novel metric, but it was the most powerful driver of variation in cost among all risk metrics. It has therefore become a very important metric for us to monitor. Each patient's serum albumin level is monitored on a quarterly basis. As a result, the slope of the serum albumin levels in our study group is positive whereas in the control group it was downward sloping. This is a quantifiable metric directly associated with changes in cost and outcome.

Overall, we maintain a focus on outcome of care rather than process. Accordingly, our quality measure focus is on:

- Hospitalization Rate accompanied by length of stay and readmission rates
- Use of Emergency Rooms rather than clinic time
- Appropriate use of biologic medications based on predefined indications and patient risk assessments

- Monitoring of medication management with assessments of drug levels and antibody levels, treat to target, site of service for administration
- Immunization maintenance
- Surveillance intervals for colonoscopy
- Use of Steroids: more than the equivalent of 10mg of Hydrocortisone per day for 60 days in any period
- Serum Albumin: level and slope of levels
- Maintenance of patient satisfaction as measured by ping response rates and independent reporting by outside entities (Press Ganey)
- Risk adjusted average Sonar Scores
- Quarterly HADS scores and CDS Healthy Days Scores

How do the above measures drive reimbursement rates?

Our current patient numbers are still small and therefore can be significantly affected by a single hospital admission. It is therefore not reasonable to financially penalize individual physicians for a single hospital admission. We have therefore developed the following methodology for physician reimbursement.

The IMH payments received from the payer are maintained in a single pool and distributed as follows:

- NCM expenses are distributed based upon number of patients followed
- Sonar platform expenses are distributed based on number of patients with reductions in payment expected if patient response rates are maintained above set levels:
 - 10% discount if response rate is maintained over 60%
 - 20% discount if response rate is maintained over 80%

Following the payment of PS related costs, the remaining distributable income from PS is distributed on the basis of a balanced scorecard which take these metrics into account.

- Eligibility into the fund is based upon completion of all fields in the CDS tools which include:
 - Risk Assessments updated annually
 - Immunization documentation
 - Steroid usage documentation
 - Biologic Usage documentation
 - Serum Albumin levels
- 1/3 based upon number of patients followed
- 1/3 based upon average Sonar Score
- 1/3 based upon patient satisfaction

Lack of need for change in payment methodology

Criterion 3: Payment Methodology (High Priority Criterion). Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM Criteria. Addresses in detail through this

methodology how Medicare, and other payers if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

The PRT is not convinced that a new payment model is necessary to achieve the goals of this model. This PRT finds that a care management fee (such as what is possible with the Complex Chronic Care Management fee or Chronic Care Management fee) alone with the standard fee-for-service payment may be sufficient. This is supported by the fact that some Medicare beneficiaries have already been enrolled in the project.

We are in agreement with this assessment. Unfortunately, the current language of the Complex Chronic Care Management Codes 99490 and 99487 are difficult to implement due to their criteria:

- Payment based upon minutes per month of clinical staff time. This process measure does not correlate with patient outcome but imposes an unwieldy verification process on the practice. It also does not reward practices for efficiencies that minimize staff time requirements.
- 2) Requires two or more chronic conditions. What if the specialist is only managing one?
- 3) Only one practitioner can bill a CCM code per month. No ability to share the CCM fee among providers. We have significant interest in sharing payments with our PCP providers.

Because of these limitations, we have used "S" codes with our commercial carrier. The patient's enrollment visit is billed with an S0280 code and the monthly ping with associated care management is billed with an S0281 code.

The PRT also notes that the proposal does not address how to manage payments when there are multiple chronic conditions and providers.

PS is a disease-based solution, not specific to any specialty or physician type. In conditions like Crohn's Disease where comorbidities are minimal, payment management is very straightforward. Since most Medicare patients suffer from multiple chronic conditions, payments will need to be shared among providers who are sharing responsibility for their management. Team based care is the ideal model. The platform is agnostic to the provider and can therefore be deployed in multi-condition, multi-provider settings.

In addition to the above three main criteria, there were four other minor issues.

Criterion 4. Value over Volume. The proposal is anticipated to provide incentives to practitioners to deliver high-quality health care.

The proposal does not sufficiently describe the mechanisms that would drive physicians to change behavior. As an example, further identification of how engagement in Project Sonar has affected physician behavior or changed standard practice patterns to reflect better care coordination is needed. It would be important to know if the presence of a care management fee is critical to any behavior change or if it is more important for the patient pings to drive behavior change.

Traditionally physicians are accustomed to addressing patients one at a time. Furthermore, once the patient is out of the office, the physician's focus is directed to the next patient. PS promotes a change in physician behavior towards population health. This is demonstrated as follows:

- Unlike using an EMR where the provider must go into a single patient chart, in PS the physician can view all his/her IBD patients on a single screen and monitor their progress with respect to Sonar Scores. The provider can drill down into an individual patient if needed. This has helped maintain a focus on population health.
- 2. Physicians can see on a real-time basis how their patient's Sonar Scores compare to that of the other providers in their practice and how their practice compares to other PS practices.
- 3. PS has resulted in the development of team-based care where a physician has an assigned Nurse Care Manager for the management of his/her patients. This has markedly improved communication between the patient, NCM and provider.
- 4. The NCM develops a one on one relationship with the patient and becomes the patient's advocate in the practice. This has resulted in high patient satisfaction.
- 5. PS uses a set of Clinical Decision Support tools which automatically appear in the workflow of care. These CDS tools contain a wealth of longitudinal information on the patient, i.e.: disease phenotype, steroid usage, biologic history, immunization history, testing history, etc.
- 6. Sonar Scores are electronically "pushed" into the EMR using an HL7 interface so that they appear in the physician's inbox as incoming lab data. This provides the physician a monthly score on every PS patient he/she is following, thus serving as a gentle reminder to the provider of each patient being followed.

The role, if any, of nonfinancial incentives was also unclear. Further, it is not obvious if office staffing arrangements might need to change in order to accommodate Project Sonar, particularly in different practice settings. While opportunities for shared savings and losses could be seen as one way to promote value over volume, the PRT is not convinced that the specific financial incentives in this model are sufficiently structured to do so. Furthermore, the proposal does not include metrics that would directly capture behavior change.

As far as office staffing changes are concerned, this will depend on the current infrastructure of the practice. In practices where there are employed nurses, PS can be implemented by repurposing existing staff. Unfortunately, there are many practices today where nurses are not utilized. We feel strongly that the NCM function is critical to the success of the program. It is the NCM who coordinates the care between the patient and the physician. The use of the SonarMD platform greatly facilitates this function, but other platforms could accomplish the same result. The care management fee greatly facilitates the repurposing of nurses to the chronic care management function.

Criterion 7. Integration and Care Coordination. Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

The proposal is for a "specialty-based intensive medical home" that seems to have little integration with other clinicians, particularly primary care providers. While PCPs could potentially access patient information from the SonarMD platform, it seems that they are more likely to receive notes via fax which reflects little integration and potentially causes an issue with care coordination. The use of Project Sonar within the GI community offers care coordination through the care management services and the SonarMD platform does enable the NCM to monitor a practice's patients and initiate physician involvement when necessary. However, that involvement appears to be largely limited to the specialist. The current proposal does not include sufficient information about how the frontline office and nursing staff would change in order to support this model, thus leaving the PRT with little understanding of how the deployment of Project Sonar might alter traditional relationships in the delivery system.

The PRT is correct that the experience of PS has been in a specialty-based intensive medical home. We do not mean to exclude PCPs, but conditions like IBD are predominantly managed by specialists. We welcome the use of PS in primary care practices and equally welcome the integration of the platform across the PCP/SCP interface. The SonarMD platform is web-based and can be used by multiple participating providers. We believe that the deployment of the SonarMD platform across all types of practices will allow more of the care of these complex patients to be provided by PCPs working in conjunction with their specialist consultants.

Criterion 8. Patient Choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

The experience of Project Sonar in the Medicare population, a patient group that traditionally has been less inclined to use mobile apps as a primary source of contact, is limited. In the model, this potential technology gap would be addressed by providing traditional phone call care management. The submitter does not provide information as to the effectiveness of telephone communication in comparison to web- or mobile-based communication for Medicare patients with Crohn's Disease.

In the two-year experience with PS, we have not seen a difference in the use of technology between our commercial and our Medicare population. Age has not been a factor for us. As far as telephony is concerned, our NCMs have been very effective using this form of communication, but it results in an increased expense on the practice.

Criterion 10. Health Information Technology. Encourage use of health information technology to inform care.

While the PRT acknowledges that the SonarMD platform is a novel use of health information technology, the platform and clinical algorithms are proprietary, which could severely limit the expansion of the model.

Although it is true that the SonarMD platform is proprietary, we do not see it as mandatory. Other platforms will be developed and can certainly be used in PS. We do not intend to force the use of the SonarMD platform. Furthermore, we welcome the sharing of expertise and data. We have submitted PS jointly with the American Gastroenterological Association as a Performance Improvement Activity under MACRA and have also signed a Memorandum of Understanding with the AGA to integrate the SonarMD Platform with the AGA's guideline driven quality measure process to provide feedback from these measures. This feedback can then be utilized to continuously improved the quality measures.

Care management algorithms must be made publicly available so that care can be improved for all. Much like what has happened with computer programming using Hadoop and GitHub we need shared computing power and an online library of care management algorithms that can be shared. The PRT finds that the model still seems to face significant interoperability challenges. The submitter notes that, in order to access notes from the specialist, PCPs would need to access a separate system or receive faxes.

SonarMD has an HL7 interface that allows us to push Sonar Scores to each practice as lab data. This can be sent electronically to both specialty as well as primary care practices. In this fashion care management can be shared across disciplines.

Our HL7 interface also allows us the ability to accept data from any EMR which can lead to sharing of quality metrics as well as other elements of clinical data.

Conclusion

PS has been a passionate pursuit of mine for five years, but it could not have succeeded on my efforts alone. My 50 partners in the Illinois Gastroenterology Group have embraced the initiative and gone the full mile in its implementation. They implemented PS long before they received any care management reimbursement from BCBS. Like a field of dreams they believed if they built it the payers would come.

Even now, most of the care management fee goes to cover the infrastructure necessary for PS's implementation. Very little passes on to the physicians. They persist based on a true hunger amongst physicians to be part of the solution and not be considered part of the problem. As time goes on, less of our income will emanate from fee for services and a larger percentage will be derived from value-based initiatives. We must be prepared for this transition.

PS has moved beyond IGG and has been deployed on hundreds of patients across the country, which has led to decreases in morbidity and cost. I was humbled by the patient testimonials that were submitted and posted on the PTAC's public comments. PS has changed patient's lives. With an approval from the PTAC and HHS, we can expand our success to other chronic diseases and across all care settings.