# Physician-Focused Payment Model Technical Advisory Committee

#### **Committee Members**

Jeffrey Bailet, MD, *Chair* Elizabeth Mitchell, *Vice Chair* 

Robert Berenson, MD
Paul N. Casale, MD, MPH

Tim Ferris, MD

Rhonda M. Medows, MD

Harold D. Miller

Len M. Nichols, PhD

Kavita Patel, MD

Bruce Steinwald, MBA

Grace Terrell, MD, MMM

May 31, 2017

The Honorable Thomas E. Price Secretary U.S. Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

**Dear Secretary Price:** 

On behalf of the Physician-Focused Payment Model Technical Advisory Committee (PTAC), I am pleased to submit PTAC's comments and recommendation to you on a Physician-Focus Payment Model (PFPM) submitted by the Illinois Gastroenterology Group and SonarMD, LLC, entitled *Project Sonar*. These comments and recommendations are required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) which directs PTAC to: 1) review PFPM models submitted to PTAC by individuals and stakeholder entities; 2) prepare comments and recommendations regarding whether such models meet criteria established by the Secretary of Health and Human Services (Secretary, HHS); and 3) submit these comments and recommendations to the Secretary.

With the assistance of HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE), PTAC's eleven members carefully reviewed Illinois Gastroenterology Group and SonarMD, LLC's proposed model (submitted to PTAC on December 22, 2016), additional information on the model provided by the submitters in response to questions from a PTAC Preliminary Review Team and the PTAC as a whole, and public comments on the proposal. At a public meeting of PTAC held on April 10, 2017, the Committee deliberated on the extent to which this proposal meets the criteria established by the Secretary in regulations at 42 CFR § 414.1465 and whether it should be recommended.

PTAC concludes that *Project Sonar* holds promise. The Committee is supportive of the novel care model put forward in the proposal. However,

members have concerns and are uncertain about some aspects of the proposal, particularly with respect to the payment methodology. PTAC believes that many of the concerns and uncertainties could be effectively resolved through limited-scale testing. Therefore, PTAC concludes that the potential benefits of the model justify moving forward with such testing. PTAC also believes that some concerns could likely be resolved through technical assistance. Because PTAC has been advised that it may not provide technical assistance, the Committee is hopeful that the Secretary would consider options for providing technical assistance to this and other submitters.

The members of PTAC appreciate your support of our shared goal to improve the Medicare program for both beneficiaries and the physicians who care for them. The Committee looks forward to your detailed response posted on the CMS website and would be happy to assist you or your staff as you develop your response. If you need additional information, please have your staff contact me at <a href="mailto:Jeff.Bailet@blueshieldca.com">Jeff.Bailet@blueshieldca.com</a>.

Sincerely,

Jeffrey Bailet, MD

Chair

Attachments

# Physician-Focused Payment Model Technical Advisory Committee

# REPORT TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

Comments and Recommendation on

Project Sonar

#### **About This Report**

The Physician-Focused Payment Model Technical Advisory Committee (PTAC) was established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to: 1) review physician-focused payment models (PFPMs) submitted by individuals and stakeholder entities; 2) prepare comments and recommendations regarding whether such models meet criteria established by the Secretary of Health and Human Services (Secretary, HHS); and 3) submit these comments and recommendations to the Secretary. PTAC reviews submitted proposals using criteria established by the Secretary in regulations at 42 CFR § 414.1465.

This report contains PTAC's comments and recommendation on a PFPM submitted by Illinois Gastroenterology Group and SonarMD, LLC entitled, *Project Sonar*. This report also includes: 1) a summary of PTAC's review of this proposal; 2) a summary of *Project Sonar*; 3) PTAC's comments on the proposed model and its recommendation to the Secretary; and 4) PTAC's evaluation of the proposed PFPM against each of the Secretary's criteria for PFPMs. The appendices to this report include a record of the voting by PTAC on this proposal; the proposal submitted by Illinois Gastroenterology Group and SonarMD, LLC; and additional information on the proposal submitted by Illinois Gastroenterology Group and SonarMD, LLC subsequent to the initial proposal submission.

#### **SUMMARY STATEMENT**

The Committee is supportive of the novel care model put forward in the proposal, *Project Sonar*. The submitters, Illinois Gastroenterology Group and SonarMD, LLC, have demonstrated success, albeit on a small scale, in a commercial population. PTAC applauds the submitters for their forward-thinking approach to serving complex patients and their progress to-date. However, members have concerns and are uncertain about some aspects of the proposal, particularly with respect to the payment methodology. The Committee believes that testing on a small scale with Medicare beneficiaries is needed to better discern whether the proposal can fulfill its promise in the Medicare population. PTAC believes that some concerns could likely be resolved through technical assistance. Because PTAC has been advised that it may not provide technical assistance, the Committee is hopeful that the Secretary would consider options for providing technical assistance to this and other submitters.

#### PTAC REVIEW PROCESS FOR THE PROJECT SONAR PROPOSAL

Project Sonar was submitted to PTAC on December 22, 2016. The proposal was first reviewed by a PTAC Preliminary Review Team (PRT) composed of three PTAC members, including at least one physician. These members requested additional data and information to assist in their review. The proposal was also posted for public comment. The PRT's findings, conclusions, and recommendation were documented in a "Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee (PTAC)," dated March 22, 2017, and sent to the full PTAC on March 23, 2017, along with the proposal and all related information. At a public meeting held on April 10, 2017, PTAC deliberated on the extent to which the proposal meets the criteria established by the Secretary in regulations at 42 CFR § 414.1465 and whether it should be recommended. The submitter and members of the public were given an opportunity to make statements to the Committee at the public meeting. Below are a summary of *Project Sonar*, PTAC's comments and recommendation to the Secretary on this proposal, and the results of PTAC's evaluation of the proposal using the Secretary's criteria for PFPMs.

#### PROPOSAL SUMMARY

The proposal describes the model as a "specialty-based intensive medical home." The model is intended to address what the proposal refers to as "high-beta" chronic diseases – those associated with high cost, high risk, and high variability in outcome and cost. The proposal focuses on a model for treatment of Crohn's disease but the submitter indicates that the model

<sup>&</sup>lt;sup>1</sup>PTAC member Rhonda M. Medows, MD, was not in attendance.

could apply to other "high-beta" diseases. The model aims to decrease Medicare costs by reducing potentially avoidable complications, emergency room visits, and inpatient admissions for beneficiaries with this type of disease.

Under the proposed model, beneficiaries would participate in an enrollment visit with a nurse care manager (NCM), be contacted ("pinged") at least once per month via smartphone or other device of their choice to submit self-assessment data, and receive follow-up from the NCM if their data indicates a potential health problem requiring intervention. If indicated, the NCM would engage the specialist physician. The model uses a communications platform, clinical algorithms, clinical decision support tools, and predictive analytics to support these activities.

Under the proposal, the Centers for Medicare & Medicaid Services (CMS) would provide the Alternative Payment Model (APM) Entity additional payments for these remote patient monitoring services – \$200 for the enrollment visit and \$70 per beneficiary per month (PBPM) for each beneficiary enrolled in the project. The APM Entity would also be eligible for shared savings up to 10% of spending and be required to repay losses up to 5% of spending based on retrospective reconciliation against a risk-adjusted target price. The model would also include stop loss provisions and outlier protections.

#### RECOMMENDATION AND COMMENTS TO THE SECRETARY

PTAC finds that the proposed PFPM has promise. However, members have concerns and are uncertain about some aspects of the proposal, particularly in regard to the payment methodology. PTAC believes that many of the concerns and uncertainties could be effectively resolved through limited-scale testing and concludes that the potential benefits of the model justify moving forward with such testing.

PTAC members are supportive of the proposal's care model and the goals it aims to achieve. The care model leverages technology to enable specialty practices to remotely monitor their patients who are at risk of complications and hospitalizations and initiate early intervention as indicated. Intervening early may avoid unnecessary emergency room visits and hospitalizations, improve patient care, and reduce Medicare spending.

Specialists tend to be financially rewarded for the number of procedures they perform. PTAC members appreciate that this medical home-like model would offer resources for and reward the management of complex patients. Members also appreciate how this model improves patient engagement in their own care by responding to regular pings about how they are faring.

Importantly, the submitter provided evidence that the proposed PFPM works, at least on a small scale, in a commercial population.

While the proposal highlights the submitters' own experience managing patients with Crohn's disease, the Committee views the model as scalable to other gastroenterology practices. In addition, the submitters indicate and PTAC agrees that the proposed model could apply much more broadly to other conditions and specialties.

Although PTAC members recognize the promise in this proposal, they have a number of concerns and are uncertain about some aspects of the proposal, particularly in regard to the payment methodology. PTAC believes that the general structure of the payment model – a PBPM payment to support a novel intervention and the accountability that risk sharing creates – makes sense, but members see a need for more work in terms of the details. Under the model, shared savings/losses are based on total cost of care. A key concern is whether the model is structured appropriately for holding providers accountable for total cost of care. Medicare beneficiaries may be more likely than the younger commercial population in which the model has been tested to have multiple chronic conditions and may be under the care of several different types of specialists. Therefore, the total cost of their care could be affected by more than Crohn's disease or the specific condition(s) targeted by the specialists through the payment model.

PTAC recognizes the need for quality measure performance to be tied to payment, an area in which the proposal is deficient. While the proposal includes quality reporting, it does not address how meeting quality measure performance thresholds will affect payment to the APM Entity (i.e., shared savings). While decreasing costs could be indicative of high quality care, if achieved by reducing avoidable emergency room visits and hospitalizations, the Committee finds that a more direct connection between quality and payment is also necessary.

Members are also concerned that this proposal may encourage "cherry picking," or avoiding complex patients with high costs. The submitters express a willingness to serve complex patients. However, the same may not be true for other providers, if the model was implemented more broadly. In addition, since the payment model is triggered by the patient's diagnosis, PTAC believes the model needs a mechanism for ensuring the accuracy of diagnosis.

The Committee is also not entirely convinced that a new payment model is necessary to achieve the goals of the model. Both the submitters and PTAC acknowledge that a new or modified chronic care management (CCM) code could support the proposed care model. (While Medicare provides payment for chronic care management services, the required elements to

bill the existing codes do not align with the proposed intervention.) A code seems administratively simpler but may be challenging for the submitter to obtain. In addition, a CCM code alone does not move providers away from fee-for-service and towards greater accountability like the proposed model would. However, the Committee is uncertain about the extent to which this greater accountability would drive behavior change versus CCM payments or other paths that do not entail the creation of a new payment model.

The Committee also has concerns related to integration and care coordination. Holding participants accountable for costs might incentivize greater integration and care coordination with outside providers. However, the Committee believes that greater specificity is needed on how integration and care coordination would be supported and who would be responsible to ensure that it took place, particularly when considering a patient population likely to have comorbidities.

In addition, PTAC is uncertain whether the new technology supported by this model will be as effectively leveraged with the current Medicare beneficiary pool. The model creates efficiency for practices by allowing patients to be pinged and submit data through a web- and mobile-based platform. Although the model allows for traditional phone calls, it is unclear how well it would work if large numbers of participants did not utilize the platform. The current beneficiary pool may be less receptive to using new technology.

PTAC finds that the proposal meets all but two of the Secretary's criteria – Payment Methodology and Integration and Care Coordination. Payment Methodology is one of the three criteria that the Committee designated as "high priority." Although PTAC's general policy is to not recommend any proposals that did not meet the high priority criteria, PTAC believes that the merits of the proposal justify a recommendation for limited-scale testing. Some of the issues may be aided by analyzing Medicare claims data that the submitters did not have. However, other concerns would be difficult to resolve without testing the model. In addition, the submitter indicates that there have been too few participants in its existing program to enable a statistically valid determination of which factors have the strongest tie to outcomes.

#### **EVALUATION OF PROPOSAL USING SECRETARY'S CRITERIA**

#### PTAC Rating of Proposal by Secretarial Criteria

Criteria Specified by the Secretary (at 42 CFR §414.1465)	Rating
1. Scope (High Priority) <sup>1</sup>	Meets criterion
2. Quality and Cost (High Priority)	Meets criterion
3. Payment Methodology (High Priority)	Does not meet criterion
4. Value over Volume	Meets criterion
5. Flexibility	Meets criterion
6. Ability to be Evaluated	Meets criterion
7. Integration and Care Coordination	Does not meet criterion
8. Patient Choice	Meets criterion
9. Patient Safety	Meets criterion
10. Health Information Technology	Meets criterion

#### Criterion 1. Scope (High Priority Criterion)

Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

#### Rating: Meets Criterion

PTAC finds that the proposed PFPM meets the criterion. The proposed PFPM addresses an issue in payment policy in a new way. The proposal requests that CMS provide payments for remote patient monitoring services supported by new technology. While Medicare provides payment for chronic care management services, the required elements (e.g. minutes of clinical staff time, number of chronic conditions, etc.) to bill the existing codes do not align with the proposed intervention. The model also moves away from fee-for-service by introducing two-sided financial risk.

In addition, the proposal includes gastroenterologists, whose opportunities to participate in alternative payment models have been limited. While the proposal highlights management of patients with Crohn's disease, the submitters indicate and PTAC agrees that the proposed model could apply to other conditions and physicians in other specialties, as well.

<sup>&</sup>lt;sup>1</sup>Criteria designated as "high priority" are those PTAC believes are of greatest importance in the overall review of the payment model proposal.

#### Criterion 2. Quality and Cost (High Priority Criterion)

Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

#### **Rating: Meets Criterion**

PTAC finds that the proposed PFPM meets the criterion. The model aims to reduce avoidable emergency room visits and hospitalizations, which would both improve quality and reduce spending. PTAC concludes that the proposed intervention and introduction of two-sided financial risk support the model's goals, particularly as the model has demonstrated success, albeit on a small scale, in a commercial population. However, PTAC believes that quality measure performance should be tied to payment, and in this area, the proposal is deficient.

#### 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 Physician-Focused Payment Model cannot be tested under current payment methodologies.

#### **Rating: Does Not Meet Criterion**

PTAC finds that the proposed PFPM does not meet the criterion. While PTAC is supportive of the intervention put forth in the proposal, the Committee has concerns regarding the payment methodology designed to support it. Both the submitters and PTAC acknowledge that a new or modified chronic care management code could support the proposed care model. (As noted above, the specifications of the current codes present barriers to their use.) A code also seems administratively simpler but may be challenging for the submitter to obtain. However, a CCM code alone does not move providers away from fee-for-service and towards greater accountability like the proposed model would. However, the Committee is uncertain about the extent to which this greater accountability would drive behavior change versus CCM payments or other paths that do not entail the creation of a new payment model.

PTAC supports the general structure of the payment model – a PBPM payment to support a novel intervention and the accountability that risk sharing creates – but sees a need for more work in terms of the details. The submitters considered whether to use total cost of care or condition-related cost of care and ended up using total cost of care. A key concern is whether the model is structured appropriately for holding providers accountable for total cost of care. Because Medicare beneficiaries are more likely than the commercial population in which the

model has been tested to have multiple chronic conditions and may be under the care of several different types of specialists, these other conditions and physicians could have a significant impact on the total cost of care.

A related concern is the opportunity for cherry picking. While the submitters express a willingness to serve complex patients, the same may not be true for other providers if the model were implemented more broadly. In addition, since the payment model is triggered by the patient's diagnosis, PTAC believes the model needs a mechanism for ensuring the accuracy of diagnosis. In addition, as noted above, the proposal is deficient in tying quality measure performance to payment.

#### Criterion 4. Value over Volume

Provide incentives to practitioners to deliver high-quality health care.

#### **Rating: Meets Criterion**

PTAC finds that the proposed PFPM meets this criterion. (The Committee also notes that this criterion overlaps with Criterion 2 and Criterion 3, so there is some redundancy in the explanation.) The proposal includes incentives for practitioners to deliver high-quality health care in the form of (1) payments to support an intervention that aims to reduce avoidable emergency room visits and hospitalizations and (2) accountability for decreasing costs, which reducing emergency room visits and hospitalizations should accomplish. Specialists tend to be financially rewarded for the number of procedures they perform. This model would offer resources for and reward the management of complex patients.

#### Criterion 5. Flexibility

Provide the flexibility needed for practitioners to deliver high-quality health care.

#### **Rating: Meets Criterion**

PTAC finds that the proposed PFPM meets this criterion. The proposal describes a particular technology that the payment would support – a communications platform, clinical algorithms, clinical decision support tools, and predictive analytics – that would provide practitioners with more flexibility in monitoring and engaging their patient population. The efficiencies gained through the use of technology would also provide practitioners with much-needed headroom to provide high-quality care. In addition, the Committee finds that participation in the proposed payment model would not require use of the specific technology proposed by the submitters but rather any technology with similar functionality.

However, PTAC is uncertain whether the new technology supported by this model will be as effectively leveraged with the current Medicare beneficiary pool. The current beneficiary pool may be less receptive to using new technology.

#### Criterion 6. Ability to be Evaluated

Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

#### **Rating: Meets Criterion**

PTAC finds that the proposed PFPM meets this criterion. The Committee notes that the major aims of the model – reducing avoidable emergency room visits and hospitalizations and decreasing Medicare costs – as well as other metrics included in the proposal are commonly tracked and evaluated through existing data sources such as claims data. Members also recognize that the technology supported by this payment model generates additional data, including a symptom score and response rates, to be monitored and evaluated. Further, the submitters have demonstrated the model's ability to be evaluated by providing results from the deployment of the model in a commercial population.

#### 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.

#### Rating: Does Not Meet Criterion

PTAC finds that the proposed PFPM does not meet this criterion. PTAC agrees that the model encourages greater care coordination within a participating practice, and that holding participants accountable for total cost of care might also incentivize greater integration and care coordination with outside providers. (As noted above, members have concerns about the allocation of responsibilities and rewards.) However, particularly as Medicare beneficiaries are likely to have multiple chronic conditions, the Committee believes greater specificity is needed as to exactly how integration and care coordination would happen across disciplines and who would be responsible to ensure that it took place.

Although the submitters describe a mechanism by which outside providers could log into their platform and data from their platform can be pushed into any electronic medical record (EMR) through an HL7 interface, some providers might not be able to implement this approach.

Physicians may not want to log into multiple systems, and vendor fees for receiving data may also present a barrier.

#### 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.

#### **Rating: Meets Criterion**

PTAC finds that the proposed PFPM meets this criterion. PTAC concludes that the proactive engagement of patients to see how they are faring would encourage greater attention to their health. Other aspects of the intervention such as identification of patients' goals and barriers, biopsychosocial risk assessment, and creation of an action plan would support the unique needs and preferences of individual patients. In addition, patients make the decision to enroll and have the option to interact with the nurse care manager via a web- and mobile-based platform or through traditional phone calls.

#### Criterion 9. Patient Safety

Aim to maintain or improve standards of patient safety.

#### Rating: Meets Criterion

PTAC finds that the proposed PFPM meets this criterion. The model involves the remote monitoring of patients to identify clinical deterioration and initiate intervention early, reducing the need for emergency room visits and hospitalization. The model also includes biopsychosocial risk assessment to help determine the appropriate frequency with which patients should be contacted. PTAC concludes that these activities aim to improve patient safety.

#### Criterion 10. Health Information Technology

Encourage use of health information technology to inform care.

#### **Rating: Meets Criterion**

PTAC finds that the proposed PFPM meets this criterion. Members conclude that the model encourages the use of health information technology to inform care in a couple of ways. First, the PBPM payment would support the use of health information technology – a communications platform, clinical algorithms, clinical decision support tools, and predictive analytics – that would help practices monitor and engage their patient population and respond

to signs of clinical deterioration. Second, the submitters' vision is that data generated from the model can aid in revising clinical practice guidelines.

However, as noted above, PTAC is uncertain about how receptive the current beneficiary pool may be to using new technology. PTAC also recognizes that the model still faces interoperability challenges. Providers could log into the submitters' platform, and data from the platform can be pushed into any EMR through an HL7 interface. However, physicians are unlikely to want to log into multiple systems, and vendor fees for receiving data may also present a barrier. Yet, these challenges are not unique to the model.

In addition, members have some concerns that the communication platform, clinical algorithms, clinical decision support tools, and predictive analytics are currently proprietary. However, the Committee concludes that success under the proposed payment model does not require use of the specific technology proposed by the submitters but rather any technology with similar functionality.

#### **APPENDIX 1. COMMITTEE MEMBERS AND TERMS**

Jeff Bailet, MD, Chair

Elizabeth Mitchell, Vice-Chair

#### Term Expires October 2017

Rhonda M. Medows, MD

Providence Health & Services

Seattle, WA

Len M. Nichols, PhD

Center for Health Policy Research and Ethics

George Mason University

Fairfax, VA

Harold D. Miller

Center for Healthcare Quality and Payment

Reform

Pittsburgh, PA

**Grace Terrell,** MD, MMM

Envision Genomics
Huntsville, AL

#### **Term Expires October 2018**

Jeff Bailet, MD

Blue Shield of California

San Francisco, CA

**Elizabeth Mitchell** 

Network for Regional Healthcare Improvement

Portland, ME

Robert Berenson, MD

Urban Institute

Washington, DC

Kavita Patel, MD

Brookings Institution
Washington, DC

Term Expires October 2019

Paul N. Casale, MD, MPH

NewYork Quality Care

NewYork-Presbyterian • Columbia

• Weill Cornell

New York, NY

Bruce Steinwald, MBA

Independent Consultant

Washington, DC

Tim Ferris, MD

Partners Health Care

Boston, MA

#### **APPENDIX 2. PFPM CRITERIA ESTABLISHED BY THE SECRETARY**

#### PFPM CRITERIA ESTABLISHED BY THE SECRETARY

- **1. Scope.** Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.
- **2. Quality and Cost.** Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.
- **3. Payment Methodology.** 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 Physician-Focused Payment Model cannot be tested under current payment methodologies.
- **4. Value over Volume.** Provide incentives to practitioners to deliver high-quality health care.
- **5. Flexibility.** Provide the flexibility needed for practitioners to deliver high-quality health care.
- **6. Ability to be Evaluated.** Have evaluable goals for quality of care, cost, and any other goals of the PFPM.
- **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.
- **8. Patient Choice.** Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.
- 9. Patient Safety. Aim to maintain or improve standards of patient safety.
- **10. Health Information Technology.** Encourage use of health information technology to inform care.

# APPENDIX 3. DISTRIBUTION OF MEMBER VOTES ON EXTENT TO WHICH PROPOSAL MEETS CRITERIA AND OVERALL RECOMMENDATION<sup>1</sup>

Criteria Specified by the Secretary	Does not meet		Meets		Priority consideration		Rating
(at 42 CFR §414.1465)	1	2	3	4	5	6	
1. Scope of Proposed PFPM (High Priority) <sup>2</sup>	1	-	3	4	-	2	Meets criterion
2. Quality and Cost (High Priority)	1	2	3	2	1	1	Meets criterion
3. Payment Methodology (High Priority)	3	3	3	-	1	-	Does not meet criterion
4. Value over Volume	1	3	4	1	1	-	Meets criterion
5. Flexibility	-	-	4	3	2	1	Meets criterion
6. Ability to be Evaluated	-	-	4	5	1	-	Meets criterion
7. Integration and Care Coordination	3	6	1	-	-	-	Does not meet criterion
8. Patient Choice	1	1	3	5	-	-	Meets criterion
9. Patient Safety	-	-	5	2	2	1	Meets criterion
10. Health Information Technology	-	1	5	4	-	-	Meets criterion

Do not recommend	Recommend for limited-scale testing	Recommend for implementation	Recommend for implementation as a high priority	Recommendation <sup>3</sup>
3	6	1	-	Recommend for limited-scale testing

<sup>1</sup>PTAC member Rhonda M. Medows, MD, was not in attendance.

<sup>&</sup>lt;sup>2</sup>Criteria designated as "high priority" are those PTAC believes are of greatest importance in the overall review of the payment model proposal.

<sup>&</sup>lt;sup>3</sup>The PTAC's Request for Proposals dated February 21, 2017, states, "In order for a submitted model to be recommended by PTAC to the Secretary, the proposal must meet each of the three criteria identified as high priority criteria by PTAC." However, members find that the merits of the proposal justify a recommendation for limited-scale testing.



**PHYSICIANS** 

December 21, 2016

LAWRENCE R. KOSINSKI MD, MBA, AGAF, FACG

JAMES STINNEFORD, MD

JOSEPH LOSURDO, MD

GREGORY GAMBLA, DO

SUNIL JOSEPH, MD

WEI M. SUN

MD, PhD, FACG

RAJESH S. PILLAI, MD

SONJA GODAMBE, MD

WILLIAM LEVIS, MD

JENNIFER DORFMEISTER, MD

KELLY WINKELMAN, ANP-BC

LOCATIONS ELGIN

745 FLETCHER DRIVE SUITE 202 ELGIN, IL 60123

ALGONQUIN

SOUTH ELGIN

600 South RANDALL ROAD ALGONQUIN, IL 60102

2000 McDonald Road SUITE 260 SOUTH ELGIN IL 60177

(SHERMAN FAMILY HEALTH FACILITY)

BARRINGTON 27750 W. HIGHWAY 22 MOB #2, SUITE 150 BARRINGTON, IL 60010 (GOOD SHEPHERD HOSPITAL)

Physician-Focused Payment Model Technical Advisory Committee c/o U.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health

Policy

200 Independence Avenue S.W.

Washington, D.C 20201

PTAC@hhs.gov

Re: Project Sonar (PS)

To: The Physician Focused Payment Model Technical Advisory Committee

The Illinois Gastroenterology Group and SonarMD, LLC are requesting review of Project sonar, an Intensive Medical Home deployed into the specialty care provided for patients with chronic disease. Since 2014, PS has been deployed by the Illinois Gastroenterology Group, a specialty practice with 50 physicians and 4

midlevel providers for patients with Crohn's Disease. It has now been implemented in multiple other GI practices across the country. We envision that

PS can be expanded to other high-beta chronic diseases and present this PTAC (Scierman Family HealthCare Facility) roposal as evidence. My contact information is shown in the signature below.

Sincerely,

Lawrence R. Kosinski, MD, MBA, AGAF, FACG Managing Partner, Illinois Gastroenterology Group

President: SonarMD, LLC lkosinski@sonarmd.com 745 Fletcher Drive Elgin, Illinois 60123 (847) 370-8878

> Tel: 847 888 1300 ■ Fax 847 www.illinoisgastro.com ■ Fax 847 888 1341

## **PROJECT SONAR (PS)**

Advanced Alternative Payment Model

Lawrence R. Kosinski, MD, MBA, AGAF, FACG

Managing Partner – Illinois Gastroenterology Group

President – SonarMD, LLC

745 Fletcher Drive

Elgin, Illinois 60123

Ikosinski@sonarmd.com

(847) 370-8878

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#### **Appendices**

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- II. Abstract: Project Sonar: Improvement in Patient Engagement Rates Using a Mobile Application Platform
- III. Abstract: Project Sonar: Validating a Cost Normalization Methodology in a Community-based Registry
- IV. Project Sonar Abstract of Distinction: Digestive Disease Week 2016
- V. Guide to the use of Crohn's CDS Tool
- VI. AGA Crohn's Disease Care Pathway Risk Assessment
- VII. SonarMD Nurse Care Manager Dashboard
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  - X. SonarMD Cost Report Graphic

#### **Project Sonar Abstract**

Project Sonar (PS) is a care management program developed by community-based physicians in partnership with a major payer to improve the management of patients with chronic disease. The key to the success of PS is the combined use of evidence based medicine coordinated with proactive patient engagement. The goal of PS is to move physicians from a dependency on fee for service medicine into value based practice. The initial chronic disease category chosen by PS was Inflammatory Bowel Disease (IBD), a family of disorders that are high cost and high risk with a frequency that has been increasing over the past few decades.

In addition to high cost and high risk, CD is also associated with a high variability in outcome and cost. We term this combination of factors as "High Beta" and believe that chronic illnesses can be stratified into high beta and low beta based upon an analogy from the financial industry.

The essential features of PS for the management of patients with chronic conditions, a PFPM, are:

- Evidence Based Guidelines are used to direct the course of care. These are embedded into the EMR through use of CDS tools
- All patients are risk assessed using a set of biopsychosocial measures
- All patients are enrolled in a web-based communication platform; if not web- or smartphone enabled, they are engaged by phone calls from the NCM
- Every patient is proactively 'touched' at least once a month; more frequently as needed
- A team based care model has been incorporated into the practice
- · Clinical and financial data are analyzed
- The care pathway is continually refined through the development of care management algorithms
- We intervene before patients even realize they need care

#### PTAC Proposal – Project Sonar

#### 1. Background and Model Overview

In the United States, chronic diseases accounts for an estimated 83% of total U.S. health spending and virtually all (99%) of Medicare's expenditures are for beneficiaries with at least one chronic condition.<sup>12</sup>

Project Sonar (PS) is a care management program developed by community-based physicians to improve the management of patients with chronic disease, using evidence based medicine coordinated with proactive patient engagement. Project Sonar was initially deployed in 2012 by the Illinois Gastroenterology Group (IGG), a 50-physician practice with locations in Cook, Lake, Kane, and DuPage counties. IGG is the largest single-specialty, non-academic, Gastroenterology practice in Illinois. As envisioned by the leadership of IGG, the goal of PS was to move physicians from a dependency on fee for service medicine into value based practice. As part of this exercise, IGG analyzed their practice demographics by conditions / diagnoses, procedures, age, payor mix, etc. and confirmed that the most significant chronic disease in a communitybased Gastroenterology (GI) practice is Inflammatory Bowel Disease (IBD), which includes Crohn's Disease and Ulcerative Colitis. When factoring in the costs of pharmaceuticals, whether physician or patient administered, IBD is responsible for almost 25% of the services generated by IGG and likely most other community-based GI Groups. IBD disorders are high cost (due to hospitalizations for complications and use of biologic medications) and high risk (loss of intestine, infections, development of cancers and extra-intestinal manifestations) with a frequency that has been increasing over the past few decades. After evaluating other chronic conditions managed by a community-based GI practice, such as GERD / Barrett's esophagus, celiac disease, and chronic pancreatitis, the group determined that Crohn's Disease (CD) was most appropriate for the development of a chronic care management program.

In addition to high cost and high risk, CD is also associated with a high variability in outcome and cost. We term this combination of factors as "High Beta" and believe that chronic illnesses can be stratified into high beta and low beta based upon an analogy from the financial industry. In finance, "beta" is a measure of a stock's volatility in relation to the market<sup>4</sup>. The market has a beta of 1.0, and individual stocks are ranked according to how much they deviate from the market. A stock that swings more than the market over time has a beta above 1.0. As beta is a measure of risk, a beta greater than one generally means that the asset is volatile.

<sup>&</sup>lt;sup>1</sup> Gerteis J, Izrael D, Deitz D, et al. Multiple Chronic Conditions Chartbook. AHRQ Publications No, Q14-0038. Rockville, MD: Agency for Healthcare Research and Quality; 2014.

<sup>&</sup>lt;sup>2</sup> Partnership for Solutions. Chronic Care: Making the Case for Ongoing Care (2010 Update). February 2010.

<sup>&</sup>lt;sup>3</sup> Kosinski L, Brill J. The Promise of Patient Self-Monitoring: An App a Day Won't Necessarily Keep the Doctor Away. Clinical Gastroenterology and Hepatology, December 2016; 1751-1752

<sup>&</sup>lt;sup>4</sup> Sharpe W. Portfolio Theory and Capital Markets. June 1970, McGraw Hill, New York NY

This same analogy can be applied to most chronic illnesses. Examples of other high beta illnesses include asthma, chronic obstructive pulmonary disease, heart failure, end-stage liver disease, and type 1 diabetes, while examples of low beta illnesses include hypertension, diabetes, and hyperlipidemia. There are high beta periods in low beta illnesses.

IGG is contracted with every major commercial payor operating in Northeast Illinois, including Aetna, Blue Cross Blue Shield of Illinois (BCBSIL), Cigna, Humana, and United. Based on their own internal analysis of data, IGG met with all the payors, and BCBSIL was willing to work with the group to analyze this issue. A review of commercial claims for 21,000 patients with a ICD-9 diagnosis consistent with CD for the years of 2010 and 2011 revealed:

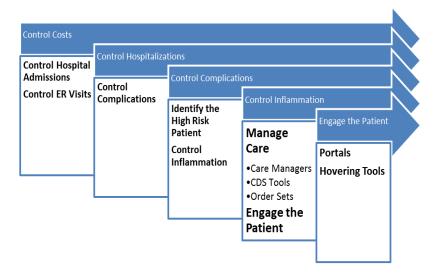
- The annual cost per patient with a diagnosis of CD was \$11,000 (2011 data)
- The overall hospitalization rate for patients with CD was 17%
- Over 50% of the expenditures incurred were for inpatient care for the treatment of complications of CD
- Although 1/3 of the total spend was for physician services, only 3.5% of the total spend was for gastroenterology care.
- Over 2/3 of the patients who were admitted to a hospital for a complication related to CD had no identifiable contact (based on claims data) with a provider in the 30 days prior to the admission

Based on this data, we asked the following questions:

- Is there a way to decrease the cost of care of patients with CD by decreasing the complication rate through better medical management?
- Is there a way to identify the high-risk patient with CD before complications ensue?
- Is there a way to channel the care of these patients to those healthcare professionals who have the most knowledge, experience and expertise?
- Is there a better way to engage our patients so that their early warning signs can be assessed even before they realize they need intervention?

While IGG was analyzing and researching these questions, the American Gastroenterological Association developed and published a care pathway for the management of Crohn's Disease. AGACDCP<sup>5</sup>. The recommendations in the pathway are as follows:

<sup>&</sup>lt;sup>5</sup> Sandborn WJ. Crohn's Disease Evaluation and Treatment: Clinical Decision Tool. Gastroenterology 2014;147:702-705.



To reduce potentially avoidable hospitalizations and to control the expense of those who are hospitalized, physicians must work with patients to control complications, which requires physicians to identify the high-risk patient and control their inflammation. This includes a biopsychosocial risk assessment that will identify the biological markers of risk and assess the patient for anxiety/depression along with their social environment.

The ensuing management requires a team-based approach deploying Clinical Decision Support (CDS) tools to guide healthcare professionals on optimal care, appropriate use of anti-tumor necrosis factor (TNF) and other biologic medications, and incorporation of Nurse Care Managers (NCMs) as the focal point in the team that was engaging with and managing the patient. Importantly it requires the engagement of the patients with the use of "hovering tools" to non-intrusively monitor the patient's symptoms, in effect creating a "sonar system" to ping them in their usual environment on a periodic basis. Collectively, the goal of PS was to engage those patients who might otherwise minimize the severity of their disease, identify patients who were depressed and/or at risk of decompensation, and optimize patients on appropriate pharmaceutical treatment as early as possible, with the objectives of improving patient quality of life and decreasing costs through reducing potentially avoidable complications, emergency department (ED) visits, and inpatient (IP) admissions.

PS was deployed in IGG in 2013, initially in a pilot study population of 50 patients with CD. CDS tools designed around the AGACDCP and a hovering tool using the Crohn's Disease Activity Index (CDAI) were deployed into IGG's NextGen electronic medical record (EMR) system. Using the EMR practice portal, patients were sent a subset of questions derived from the CDAI at the beginning of each month. This subset of the CDAI returned a score (Sonar Score) that applied a numeric value to the patient. At the end of the first year, the hospitalization rate for these patients decreased from 17% to 5%.

IGG presented the data from this pilot to BCBSIL. Based on the findings from the pilot, BCBSIL partnered with IGG to create its first specialty-based Intensive Medical Home (IMH). Using a model similar to what it had deployed in its primary care PCMH, BCBSIL attributed 303 patients with CD to IGG of which 185 were enrolled, and the IMH project, which went live on Dec. 1, 2014 was based on the clinical structure described above. The practice receives a supplemental per member per month (PMPM) payment to cover the infrastructure for participating in PS. The PMPM payment is additional to fee for service payment and varies on an annual basis, adjusted based upon mutually agreed-upon goals for the clinical and financial performance of the patients enrolled. The practice receives one year of historical claims data on its attributed patients and quarterly medical and pharmacy claims data going forward. The practice is responsible for calculating the performance of physicians at an individual, strategic business unit (SBU), and practice level, including comparison of BCBSIL patients depending on their level of engagement ('pinger' vs. 'nonpinger') and comparison to patients enrolled in other commercial and government (Medicare, Medicaid, Tricare) programs.

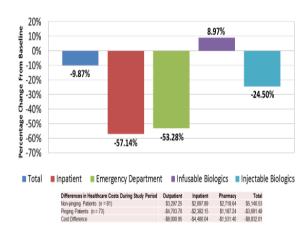
Early on, it became clear that the EMR patient portal would not sustain the level of patient engagement required for adequate care. It was replaced with a web and mobile-based platform which includes interactive text messages to patients, and patient response data which drops directly into the EMR using a HIPAA-compliant HL7 interface. Patient engagement increased from 27% to 75-80% which has now been sustained for over 20 months.

The initial first full year of clinical, financial, and patient engagement data for PS are shown in the graphic below which was presented as a Distinguished Abstract at Digestive Disease Week 2016:

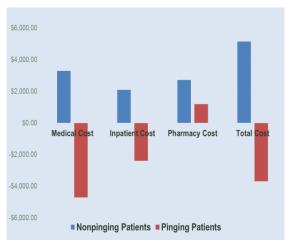
The data below are normalized to Medicare payment to emphasize true utilization rates. They show:

- A net decrease in cost of 9.87% even with an 8.97% increase in infusible biologics and Net of PMPM payments to the practices
- A 57.14% decline in inpatient costs driven by an equivalent decline in admissions/complications

## Change in Crohn's-related Normalized Payments From Baseline (Digestive Disease Week, May 24 2016)



These financial results are highly dependent upon the patient engagement. When we filter our patient population by those who respond to at least 50% of their monthly surveys (pingers) vs. those who do not respond (nonpingers), the cost differential of care falls 18% in the Pinger group whereas it rises 23% in the nonpinger group. This 41% difference in cost is shown in the figure below.



Thus, the cost savings is highly correlated to patient engagement, as it is derived from those patients who respond. Patient engagement is key to the success of PS and for the care of patients with chronic disease. Our results, which we believe are generalizable to other highbeta chronic conditions and to high beta periods in low beta conditions, lead to a model that must incorporate the use of evidence based medicine and, more importantly, must provide for ongoing patient engagement which is integrated into the workflow of care.

Key to the success of a management program for a chronic condition must be the use of appropriate risk measures. Every patient in PS is initially assessed using the risk assessment tool embedded in the AGACDCP, which includes 26 biopsychosocial risk metrics in three categories: Inflammation Risk, Disease Burden Risk and Comorbidity Risk. Multiple linear regression analyses of each risk measure against the Crohn's Related Cost of Care has helped us to identify which measures hold predictive value. This has led to further refinement of the processes within PS.

A process overview of PS is shown below:



Project Sonar: Process Overview

The essential features of PS for the management of patients with chronic conditions, an APM, are:

- Evidence Based Guidelines are used to direct the course of care. These are embedded into the EMR through use of CDS tools
- All patients are risk assessed using a set of biopsychosocial measures
- All patients are enrolled in a web-based communication platform; if not web- or smartphone enabled, they are engaged by phone calls from the NCM
- Every patient is proactively 'touched' at least once a month; more frequently as needed
- A team based care model has been incorporated into the practice
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#### 2. Scope of Proposed APM

This proposal to the PTAC will expand CMS's APM Portfolio in the following ways:

- It will move providers, especially specialists, from fee for service to reimbursement based on value based payment methodologies. It is addressing an issue in payment policy in several ways:
  - Moves patient care from reactive to proactive.
  - Focuses on early identification of potential problems and complications, encouraging 'preventive' management
  - Rewards physicians and other qualified healthcare professionals for 'doing the right thing' in a team-based manner, as opposed to reimbursement solely on an RVU-based methodology.
- It will promote "cost sensitivity" in specialist providers who are currently almost exclusively paid on a fee for service basis. This will promote the inclusion of APM entities for specialists whose opportunities to participate in APMs has been limited.
- It will link payment for specialist services to clinical, financial, and patient reported outcomes.
- It will allow specialists to participate in value based care outside of an ACO / MSSP / CRC+ model.
- It will allow physicians to participate in value based care for chronic conditions that are not triggered by a surgical procedure on an inpatient or outpatient basis.

Specialists want to be part of the value based solution but have not been fully able to exert the powerful force they have on cost containment and care improvement. The majority of CMS / CMMI initiatives to date have focused on ACOs, primary care based models, or conditions

triggered by a hospital procedure (orthopedic, cardiac). This has left the specialist out of the solution and kept them as part of the problem.

The patient has also been left out of the solution. Few value based models built around ACOs maintain a focus on patient engagement as a value-added solution. This is exacerbated by initiatives based on hospitalization triggers which do not have an outpatient focus on chronic management.

Most serious chronic illnesses are managed by specialists who are still paid under fee for service. PS shows how a specialty group in partnership with a major payer can move from FFS to value-based care and demonstrate cost-savings with improved patient quality of life. We believe this model, which has been proven in patients with IBD, is applicable to other conditions.

Although PS focused on CD, this model can be applied to other chronic illnesses. As noted earlier, we believe that chronic illnesses can be stratified into high beta and low beta. Some chronic diseases, like diabetes mellitus, hypercholesterolemia and hypertension, can be slow and indolent in the expression of their symptoms and morbidities, which we term as "low-beta" diseases. Other conditions, such as inflammatory bowel disease (IBD) are "high-beta" conditions that are not as forgiving in their disease progression<sup>67</sup>. There are several high-beta conditions including asthma, heart failure, chronic obstructive pulmonary disease, end-stage liver disease, rheumatoid and psoriatic arthritis, cancers, malnutrition and other conditions where patients are at risk for frequent, potentially avoidable, emergency department visits and hospitalizations<sup>8</sup>. Even diseases like diabetes may have high beta periods, such as the period following an admission for diabetic ketoacidosis or when patients have poor control of / high fluctuations in blood sugar / hemoglobin A1c levels. Although most of the chronic care of patients with low beta diseases can safely be provided by PCPs, the intervening high beta periods most often require the care of a specialist. The PS platform can be applied to high beta illnesses as well as the high beta periods embedded in the management of low beta chronic diseases.

We believe that PS has applicability to many patients with chronic disease and would be appropriate for use by primary care and specialist physicians and qualified healthcare professionals, both cognitive and procedural.

<sup>&</sup>lt;sup>6</sup> Natarajan Y, Kanwal F. Pay for Performance in Chronic Liver Disease. Clin Gastroenterol Hepatol. 2015 Nov;13(12):2042-7.

<sup>&</sup>lt;sup>7</sup> Fortune BE, Golus A, Barsky CL, et al. Linking a Hepatology Clinical Service Line to Quality Improvement. Clin Gastroenterol Hepatol. 2015 Aug;13(8):1391-5

<sup>&</sup>lt;sup>8</sup> Kosinski L, Brill JV. The Promise of Patient Self-Monitoring: An App a Day Won't Necessarily Keep the Doctor Away. Clinical Gastroenterology and Hepatology 2016; 14: 1751 - 2

#### 3. Quality and Cost

Value can be defined as Quality/Cost. Since Quality = Outcome, value can be further defined as Outcome/Cost. The perception of care is essential to the measure of value, so the most appropriate definition of value is: Value = (Patient Outcome + Patient Satisfaction)/ Patient Cost.

The triple aim's value today has refocused us on Population Health. So, the previous patient based equation applied to a population would be:

PS applied to patients with chronic disease can provide this value through improving quality and lowering cost. Quality can be improved through:

- Use of Evidence Based Guidelines to support a focus on outcomes.
  - PS has demonstrated a significant decrease in complications, hospital admissions and emergency department visits using a model which is applicable to other chronic conditions.
- Improved Patient Satisfaction through targeted patient engagement.
  - Patients engaged through PS maintain a very high level of satisfaction with the program. They are benefitting from "Concierge Medicine" without the extra expense.
- Proactive Patient Engagement

Proactive patient engagement coupled with clinical surveillance and intervention is critical to the successful management of patients with chronic disease. Patients with chronic disease often surface only when they recognize they are in trouble and realize they cannot repair their situation themselves. Patients with high-beta diseases can rapidly deteriorate, resulting in hospitalization and complications<sup>910</sup>. Patients with CD frequently minimize their own

<sup>&</sup>lt;sup>9</sup> American Hospital Association. Examining the Drivers of Readmissions and Reducing Unnecessary Readmissions for Better Patient Care. September 2011. Washington, DC

<sup>&</sup>lt;sup>10</sup> Hines AL, Barrett ML, Jiang HJ, et al. Conditions With the Largest Number of Adult Hospital Readmissions by Payer, 2011. HCUP Statistical Brief #172. April 2014. Agency for Healthcare Research and Quality, Rockville, MD.

deteriorating symptoms; they may present too late at which time morbidity has occurred and significant medical and/or surgical care must be provided. PS has demonstrated that patient engagement is critical to avoiding these occurrences.

#### 4. Payment Methodology

The payment model of PS represents negotiation of a transition from fee-for-service to fee-for-value for physicians who may not ready or able to take on full risk, but are capable and should be ready to accept accountability for the care they provide. PS will facilitate the development of accountability for the care of the patient with chronic disease and will promote a decline in the variability in the cost of care of these patients.

The Structural Model of PS is detailed below:

### Project Sonar Structural Model

#### Provided by Payer

- · Attribution list of patients
- Data
  - o Baseline claims data for 12 months prior
  - o Quarterly claims data going forward
- Payments
  - o Enrollment Visit: \$200 (NCM Visit)
  - o Care Management Payments \$70 PMPM
- Performance Measurements Annually assessed
  - o Outpatient Medical Costs
  - Inpatient Cost
  - o ER Visit Cost
  - Biologic Cost
    - · Infused Biologic Costs
    - · Injected Biologic Costs
  - Other Cost

#### Provided by the Practice

- Clinical Team
  - Medical Leadership
  - Nurse Care Managers: One NCM FTE per 200 patients
  - Patient Care Coordinator
- Initial Care requirements
  - Every patient to have an Enrollment Visit NCM
  - Program Goals and their Barriers
  - o Anxiety Depression Assessment
  - o Action Plan
  - Physician Visit
    - · Review of Enrollment Visit
    - · Risk Assessment
    - · Review of Action Plan

#### Ongoing Care requirements

- o Every patient must be "touched" monthly
- NCM reviews each patient's monthly ping and reports to MD
- o MD must respond to needed care

In the PS APM we are proposing a prospective payment model with retrospective reconciliation. PS is based upon a chronic care management (CCM) model combined with proactive patient engagement. Physicians who voluntarily choose to participate with the model would continue to have their services reimbursed through the MPFS. Target prices are compared to the actual cost of the care provided. Payment adjustments are based on quality and financial performance. In the case of cost savings, the shared savings component of the payment would be paid to the physician entity. In a situation where the physician's attributed

costs overrun the expected target, the physician would be required to repay losses up to the agreed upon limit in its contract with CMS. To protect against catastrophic losses, the model will build in stop-loss provisions and outlier protections.

Participating providers would also be required to contribute based upon their agreement with PS as the APM entity. A monthly payment for non 'face-to-face' services by clinical staff, overseen by the physician, is essential for the successful deployment of the model to cover the infrastructure costs required.

There are initial and ongoing costs for dedicated NCMs and ping coordinators (clinical staff), IT expenses for incorporation of CDS tools into the EMR workflow and deployment of the patient engagement platform and data management. These are detailed below:

•	NCM Cost:	\$25 PMPM
•	Ping Coordinator	\$12 PMPM
•	IT Platform	\$20 PMPM
•	Medical Director	\$2.50 PMPM
•	Total Cost	\$59.50 PMPM

The CCM payment is designed to cover the cost of deployment of the care management infrastructure not to provide supplemental income to the practice. Incentives to the practice will be generated by the sharing of cost savings derived from a retrospective adjust. A Performance Based Adjustment (PBA) is made based upon this retrospective cost reconciliation. If savings are favorable, the PBA will represent a supplemental payment to the practice. This will be capped at 10%. If performance is poor and costs are excessive based on risk adjusted norms, then the PBA would be negative up to a cap of 5%.

This payment structure should be viewed as one designed to promote a continuous process of value generation over time. We anticipate that going forward many more value-based initiatives will be necessary to continue to move the cost curve down. Episode and procedural bundled payments will be necessary as well as consolidation in NCM functions. The goal will be to gradually push cost down until a convergence to an ideal mean can be accomplished.

#### 5. Value over Volume

Volume based drivers have dominated physician practices for the last 50 years. Since "every system is perfectly designed to get the results it gets" <sup>11</sup>, medical practices are designed to "do more". In primary care practices this correlates to the metric: patients seen and RVU generated per hour. The obvious challenge is to maintain quality of care when the physician or qualified healthcare professional is seeing 4 or more patients per hour, especially if the patient has multiple co-morbid conditions, complex medication regimens, psychosocial issues, etc. There is

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<sup>&</sup>lt;sup>11</sup> Conway E, Bataiden P. Institute for Healthcare Improvement; August 21<sup>st</sup>, 2015

a limit to the productivity of a practice, whether primary care or specialist, which cannot be solved through use of qualified healthcare professionals.

While specialists may be more procedural, they are equally as volume driven. Data from IGG shows that over 54% of the revenue of a community-based GI practice comes from screening (G0105, G0121), diagnostic (45378), and procedural colonoscopy (45380, 45384, 45385), primarily related to colorectal cancer (CRC) screening, diagnosis, and surveillance. Many Gastroenterologists have developed a very efficient focused-factory model for performing this procedure.

Why should a GI move from this model to one based on value? Colonoscopy is a mature service; CMS has adjusted procedure wRVU downwards in CY 2016 and 2017, revenue is declining and costs are rising, compressing margins. Alternative methods for CRC screening are available which, in a population based environment, might lead to a shift from procedural to diagnostic colonoscopy with a corresponding decline in the volume of colonoscopy. Anticipating this trend, Project Sonar was developed to provide GI physicians with an option to improve care based on value based chronic disease management, rather than attempting to perform more procedures.

In our initial review of commercial payer claim data from 2010 and 2011, the average cost/patient with CD was \$11,000, which includes professional, laboratory, imaging, hospital / facility, and pharmaceutical costs. The average yearly reimbursement to a GI for managing these patients was \$385, which includes only professional fees for office visits, procedures, and supervision of physician-administered infusions. Similar to oncology, physician administered infusions represent an additional source of revenue to the practice, while prescribing a patient self-administered drug would not generate any practice revenue.

The problems in today's FFS model are obvious and include:

- Physicians are compensated more to do more. Physicians are incented to perform more procedures where the revenue per RVU is higher. By revising the 2017 fee schedule to pay a facility more for colonoscopy procedures (e.g. 45380, 45385) and less for screening / diagnostic procedures (e.g. G0105, G0121, 45378), CMS has potentially created an incentive for physicians who own an ASC to perform more procedural services.
- As the per-minute compensation for cognitive services is less per RVU compared to
  procedural services, many of these visits have been relegated to qualified healthcare
  professionals (nurse practitioners, physician assistants) in the practice who might not
  detect early signs of deterioration in a patient. This creates a paradoxical situation
  where the most knowledgeable member of the healthcare team is busy performing the
  most repetitive and least cognitive task (procedures) while the more complex cognitive
  services are performed by less-trained professionals.
- Prescribing infused biologics to increase practice revenue.

- The patient is seen every 6-8 weeks when they come in for their infusion. If that infusion is performed in an office setting where the physician sees the patient, our data suggests that the hospitalization rate is much lower than if the infusion is performed in a setting (hospital outpatient or, for commercial patient, free-standing infusion center) where the patient is not seen by their provider involved in the ongoing management of their condition.
- Patients do not want to disrupt their lives every six to eight weeks to come in for an infusion. This results in lost productivity at work, use of PTO days and time away from family. For these and other reasons, patients may prefer selfadministered drugs, which creates a potential management issue as the patient is not being monitored as they would if they were coming in for an infusion.
- On a total cost basis when looking at the cost of drug and infusion, the cost of
  infusible biologics is higher than the cost of self-administered agent, which does
  not consider the lost productivity cost. This must be balanced by the higher
  hospitalization rate with self-administered agents due to a loss of ongoing
  communication with the provider.

PS was developed to address these issues. How does PS move this to value?

- The provider in PS is compensated a prospective payment fee in addition to their usual FFS compensation. In our commercial model, this represents approximately \$600 per year to the provider, which is not significantly different from the approximately \$490 per year were the physician to bill CPT code 99490 (chronic care management). The physician is encouraged to continue office visits for the patient, and to provide procedural services when clinically indicated, such as for CRC screening / surveillance.
- The physician practice is responsible for paying the NCM and ping coordinator and data management out of the monthly CCM payment.
- Expenses for all procedures are paid under a bundled payment methodology.
- Physicians are encouraged to utilize anti-TNF and other biologics based upon the most efficacious agent, not the one that generates the most revenue to the practice. The PS system facilitates patient engagement and communication regardless of the site of service.

Performance data using PS in a commercial population has shown a "Net" 9.87% savings. Based upon the \$11,000 cost per patient, this amounts to a savings of over \$1,000 per patient. This is net of the monthly CCM payments and is a normalized savings based upon Medicare Payment Rates. The combination of prospective CCM payments which support care infrastructure of NCMs combined with the use of the Sonar Platform facilitate this overall savings and its improvement in the quality of life of its patients.

#### 6. Flexibility

PS represents a flexible and scalable platform upon which to expand its use to most all practices. To date, we have installed the common PS platform in 20 GI practices across the country representing approximately 600 physicians in 12 states, including community and academic practices.

The "glue" that binds the PS practices is the use of the web and mobile-based platform, which represents a single database of provider driven and patient driven metrics. A web-based platform which is both EMR and smartphone device agnostic allows PS to apply changes centrally and distribute automatically to all sites. The results of Sonar Scores are pushed into EMRs as lab data using a HL7 interface.

The PS platform has been used for research on clinical and pharmacological outcomes and effectiveness. For example, the network of PS practices has been leveraged to study the effects of oral therapies for irritable bowel syndrome as well as IBD, and to assess whether assessment of small bowel mucosa correlates with clinical and CDAI findings.

PS requires the practice to change its focus from 'passive-reactive' to proactive population health. Instead of a "one patient at a time" passive focus, waiting for the patient to contact the physician with new or intensifying symptoms, the PS practice is focused on the population of patients. The practice, and the patients with a disease process, are actively engaged to improve the care of the patient. This requires infrastructure changes such as the incorporation of NCMs and the ping coordinator.

We believe that a similar care management infrastructure is applicable to other illnesses. We further believe that PS is agnostic to the specialty and is applicable to other chronic illnesses, and can be used by primary care and specialist physicians involved in the care of patients with high beta chronic disease or the high beta periods in patients with low beta conditions.

#### 7. Ability to be evaluated

Evaluation of any new care model is essential to validate its value. PS has been under evaluation since its inception. The following financial metrics are monitored on a regular basis:

- Average total cost/patient
- Average inpatient cost/patient
- Average Emergency Room cost/patient
- Average biologic cost/patient both infused vs injected

Total cost from a commercial plan is a misleading metric as it must be normalized to Medicare Payment Rates to minimize the site of service differential. That is not to say the site of service is not important, it must be minimized as well. By using a single payment methodology, utilization can be better assessed.

Ultimately the most important outcome is the improvement in the quality of life of the patients with the disease in question. Financial measures alone may not reveal the entire patient benefit. We must always place higher value on the costs incurred for disease morbidity. An example is the cost of inpatient care vs the cost of biologic therapy. Despite the expense of the latter, it does not come with the suffering of the morbidity of disease.

Outcomes driven quality metrics, difficult to develop, have slowed the movement from volume to value. Since PS has a unique access to both quality as well as claims data it has been able to develop predictive models based on how changes in quality metrics effect cost. Utilizing the 26 risk assessment metrics in the AGACDCP, PS ran multiple linear regressions of each metric against the Crohn's Disease Cost of Care. This has allowed for the development of a mathematical model which assigns a relative strength to each metric with respect to its ability to control the cost of care.

CDCP Risk Factor	Odds Ratio	95% Confidence Limits		
		Lower Limit	Upper Limit	
Inflammation risk: Albumin	19.4	3.9	97.8	
Inflammation risk: Joint pain	5.7	2.2	14.5	
Comorbidity risk: Inflammation	11.5	1.5	87.8	
Comorbidity Risk: Stricturing	5.4	2.2	13.4	

Each risk assessment metric has a relative value. Patients can be profiled with this scoring methodology and placed accurately in risk categories. An example would be the use of serum albumin levels as a predictive value for risk. We have shown that changes in serum albumin are predictive of 19.4% of the variation in cost of care for CD<sup>12</sup>. Patients are monitored quarterly for serum albumin level changes.

We continue to refine this mathematical model, which will benefit from a larger "n" of patients. This model enables rating of each physician and NCM performance on a risk adjusted basis. Ping response rate is critical to the outcome of PS; provider and NCM specific ping response rates can be used as a metric for performance.

We have developed an upside risk revenue share model which creates the proper incentives for physician behavior. Working with physician groups in a variety of practice and geographic settings, we have arrived at the following formula:

- 33%: based on number of patients followed
- 33%: based on the ping response rate
- 34%: based on the risk adjusted cost of care

<sup>&</sup>lt;sup>12</sup> Kosinski L, et al. Validation of AGA Crohn's Disease Care Pathway Risk Assessment Metrics Against Crohn's Related Cost. Abstract. Inflammatory Bowel Diseases 22 S23-24 March 2016

With additional data and additional participating practices, we believe this formula can and will be adjusted in the future to promote optimal value-based behaviors.

#### 8. Integration and Care Coordination

The success of PS rests on the deployment of a team-based care infrastructure. MD can no longer stand for "My Decision". To successfully manage the patient with a chronic condition, physicians and qualified healthcare professionals, NCMs, Ping Coordinators and ancillary personnel such as behavioral health and pharmacists are required.

At present, the current care management model for PS centers around the NCM, who is the most important component of the team. Based on data from the Case Management Society of America, each FTE NCM should be able to follow 150-200 patients<sup>13</sup>. Our data shows that using PS's web and mobile patient engagement platform, this number can be safely increased to 250 patients per FTE NCM. Practice management data indicates that one NCM can provide support to multiple physicians and qualified healthcare professionals in the practice. For solo and smaller practices that might not have the patient volume to support a dedicated NCM, we believe that a shared-service model could support such practices.

The NCM relationship begins at enrollment when the patient comes in for a "Supervisit". At this visit, patients are introduced to the NCM and queried as to their personal goals for the program. Barriers to accomplishing these goals are identified and an action plan generated. Patients are rated with respect to depression/anxiety using a PHQ-2 tool as these components affect all chronic diseases. Diet histories are generated with action plans for nutritional support. At the conclusion of the initial visit, the patient is seen by the physician or qualified healthcare professional who reviews the details of the Supervisit and all parties sign off on the action plan.

After the initial Supervisit, ongoing management begins. The PS platform provides a desktop to the NCMs where their patients can be monitored together as a population. The NCM follows the Sonar scores of the patients and contacts all patients whose scores fall out of standards, or who does not respond to their 'ping' within a predetermined amount of time. Based on the patient responses, if required the NCM goes into the practice EMR and initiates a communication with the physician or qualified healthcare professional. Patients whose scores indicate that they are deteriorating are contacted and engaged with the physician or qualified healthcare professional, either in-person or telephonically. Precision care is being managed proactively and constantly. Patients are engaged and physician services are initiated as needed by the NCM.

<sup>13</sup> Case Management Society of America and National Association of Social Workers. Case Management Caseload Concept Paper: Proceedings of the Caseload Work Group. October 30, 2008. Available at <a href="http://www.cmsa.org/portals/0/pdf/CaseloadCalc.pdf">http://www.cmsa.org/portals/0/pdf/CaseloadCalc.pdf</a>

All care, from the Supervisit through the ongoing care, is contained in the same relational database. Reports can be generated from queries developed by the PS leadership team. Interactions between the members of the team can be monitored and rated. The platform provides the ability to rate NCMs separately from providers.

Each practice should have a clinical staff member who functions as a "ping coordinator", monitoring the ping process on a regular basis. This person monitors who is entering and exiting the program.

The issue of integration with PCPs and other specialists needs to be discussed. We see this model as being integrated into the structure of the entire care team. In pure high beta illnesses like CD, the specialist may be the only member of the team that receives the PMPM payment. In high beta periods of low beta conditions, the specialist will receive the PMPM only during the high beta period. The bottom line is that the provider managing the care of the chronic illness in question receives the payment. When comorbidities exist which require management by multiple specialists, then multiple management fees may be necessary.

#### 9. Patient Choice

PS is focused around the needs of the patient. In fact, the focus of PS *is* the patient. Our data and results have shown that the patients prefer the engaged infrastructure of PS - their NCM functions as their own personal care coordinator, or "concierge care within a managed environment." Patient satisfaction is high; PS has maintained a 75-80% sustained patient ping response rate over 2 years.

We learned this that hard way. In the first six months of PS, we used a patient portal for our patient communication. This was not ideal and the patients did not like logging in to the portal to obtain their surveys. The EMR portals are cumbersome, inflexible, and slow to align with advancements in technology (e.g. new smartphones and devices used by consumers). In June 2015, we switched to a web and mobile-based platform developed by PS that utilizes smart phone technology, which has been very well received by the patients and is clearly their choice of communication.

For the 20-25% of the patients who either do not have a smart phone or choose not to use one, we use more conventional means of communication. A small number of patients prefer the portal. Telephone calls from the NCM asking the patients the questions in the survey are used when other means are not possible. As we serve a population in whom English might not be the primary language for some patients, PS is in process of translating the questions into Spanish and using ATT Language Line for others. In the end, we "touch" every patient every month.

Approximately 24% of patients are deemed depressed or anxious at enrollment. These patients require a higher level of service which can be provided through PS. As our data shows that

patients with behavioral health issues is associated with a 13% higher cost of care, they are a major focus for the NCM. These patients may receive multiple calls and touches during the calendar month. In the end, PS is the patient's choice. High levels of patient satisfaction exist.

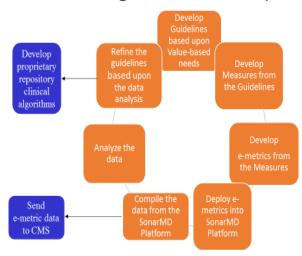
#### 10. Patient Safety

PS must be considered a Sonar System for patients with chronic disease. It is like looking out at the ocean. Think of the patients as submarines, submerged and running silent and deep. They only surface when they are in trouble which means two things will need to happen for them to surface: they recognize they are in trouble, and realize they can't get out of trouble on their own. Unfortunately, patients make mistakes on both issues and their safety can be compromised. In high beta diseases like Crohn's Disease or end-stage liver disease, there is not much room for error. They surface in deep trouble and must be brought in to port (the emergency department) which usually results in hospitalization.

Our data shows a significant improvement in patient safety with implementation of PS, as demonstrated by the significant decrease in emergency department use and hospitalization rate. The close patient engagement built into PS minimizes patient safety issues.

The algorithms which are built into PS are a key component of our success. The NCM desktop is alerted when a patient's Sonar Scores fall out of safety ranges. These ranges are based upon a continuous process of refinement / development of algorithms:

# The SonarMD Algorithm Development Cycle



#### 11. Health Information Technology

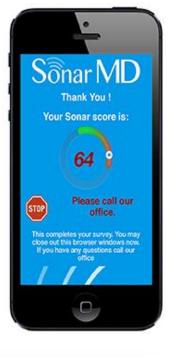
PS is built on an HIT platform which utilizes both web and mobile-based technology to communicate with providers, their staffs and their patients. It is cloud-based and agnostic to the operating system of the handheld device as well as the practice EMR. Although not an EMR, the PS platform integrates with all EMRs by pushing sonar scores through to the EMR as lab data using an HL7 Interface.

Patients using the PS platform receive monthly "pings" on the device of their choice: smartphone, tablet, PC, etc. Some patients who do not have access to this technology receive their communication via telephone.

The strength of the mobile platform lies in its ability to provide immediate feedback to the patient. Since it is a web-based platform communicating to a SQL database, algorithmically generated responses can provide patients with immediate feedback. If the patient's Sonar Score triggers one of the algorithms, the patient is instructed to contact the office of the practice. Concurrently, the NCM in the practice receives the same notification and most often contacts the patient before the patient does. This provides not only an excellent communication tool, it provides the patient with a sense of security that someone is constantly monitoring their condition.

On the practice side, the NCMs utilize a set of desktop

templates where they can monitor the performance of each of their patients as well as their assigned patients in aggregate. Sonar Scores are color coded based on algorithmic rules. See Appendix VII for full images. Unlike an EMR where patient charts are opened one patient at a time, the Sonar Platform is designed for population health providing the NCM and the physician with the ability to see all of their PS patients in a user-friendly interface.

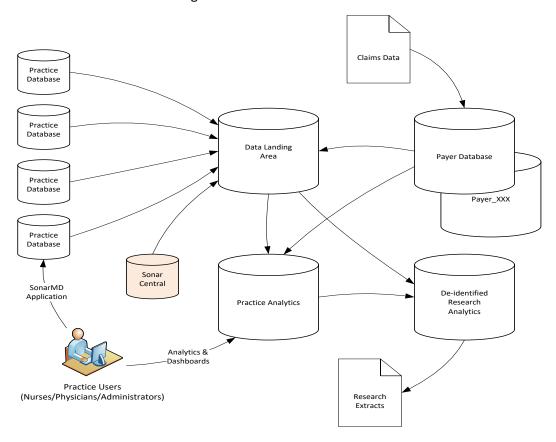




Each practice participating in PS has its own sub-platform, thus they cannot comingle data from other practices. At a central level, PS's "Sonar Central" can pull data into a central repository for query creation and reporting. The ability to aggregate and analyze data from practices

across the United States has in effect created a GI Registry for IBD. PS is able to monitor trends across the population, study clinical factors related to outcomes, and provide guidance and recommendations back to the practices. It is also our vision to use these capabilities to further drive clinical decision support at the time of engagement and evidences based medicine across the specific disease state(s).

Safety and security are maintained through the appropriate use of encryption and use of firewalls. This is shown in the diagram below.



The PS' IT infrastructure lends itself to being expanded and scaled as necessary to accommodate multiple practices and disorders. Safety and security are maintained through the appropriate use of encryption and use of firewalls. Sonar has a full HIPAA compliance program in place to safeguard access and use of the PS data.

There are currently over 600 in 20 large GI practices across the country who have implemented the SonarMD platform. All of the data from these practices is contained in the above structure in a safe/secure environment. This infrastructure is perfectly positioned to be expanded to other disease processes and practices in other specialties.

#### 12. Supplemental Information

The expansion of Project Sonar beyond the Illinois Gastroenterology Group necessitated the formation of an entity to provide the necessary structure for a national project. SonarMD, LLC is a Delaware LLC founded in 2014 by physicians dedicated to the development of chronic care management tools. Through development of its provider focused CDS tools and its patient engagement digital platform SonarMD provides medical practices with a patient friendly infrastructure for population health.

The medical practices currently using the SonarMD digital platform constitute the SonarMD Medical Group (SMG). Each practice is contracted with SonarMD under identical contractual arrangements, and nominates a member to the SMG advisory board. We anticipate that as PS grows, advisory groups will be organized around specialty and condition.

We have considered whether SonarMD, LLC could be the APM entity that contracts directly with CMS. In this scenario, the risk arrangement for the APM entity including, total risk and stop-loss provisions would be agreed upon in the APM entity's contract with CMS. Infrastructure expenses would include:

- Development of a CCM payment designed to cover the infrastructure necessary to implement the PS platform: NCMs, Ping coordination, IT Platform
- Mechanisms for claims processing under prospective bundled vs. retrospective payments.
- Claims data reporting
- Quality reporting based upon mutually agreed upon measures and metrics. These
  measures will include MIPS measures as well as PS derived measures. An example for
  IBD would be as follows:

Category	Description
NQF 128	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
NQF 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
	Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related latrogenic Injury
NQF 271	- Bone Loss Assessment:
	Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before
NQF 275	Initiating Anti-TNF (Tumor Necrosis Factor) Therapy
PHQ 2 Q1	Little Interest or Pleasure in doing things?
PHQ 2 Q2	Feeling Down Depressed or Hopeless
Lab	Serum Albumin
Lab	Serum Hb
Lab	Fecal Calprotectin
Lab	C-reactive protein
Lab	Endoscopic Assessment of Disease Activity
Sonar	Ping Response Rate
Sonar	Average Sonar Score

Financial reporting measures as previously addressed

# **Appendices**

 Abstract: Validation of American Gastroenterological Association's Crohn's Disease Care Pathway

Project Sonar: Validating Predictive Algorithms and Risk Scores for IBD Outcomes Using a Community-Based Registry and Patient Engagement Data

# Background

Project Sonar is a community-based registry and disease management program developed to improve clinical and economic outcomes in Inflammatory Bowel Disease (IBD). This cloud-based program integrates monthly patient-reported symptoms and health-related quality of life (HRQoL) information with clinical data delivered through electronic medical record derived Clinical Decision Support tools (CDS). These fields are then combined with payer provided-claims data to provide comprehensive, real-time information to physicians and patients on current symptoms and health status, as well as composite 'Sonar' scores. The CDS tools were developed using the American Gastroenterological Association's Crohn's Disease Care Pathway (CDCP), and Ulcerative Colitis Care Pathway, both of which determine treatment guidelines for Crohn's Disease and Ulcerative colitis (UC), respectively. The objective of this project was to verify and measure the variation of data within Project Sonar, validate the CDCP and UCCP guidelines, and Sonar risk scores using the real world data collected via Project Sonar and healthcare claims of a subset of patients. The objective of this presentation is to detail the methods used in this process.

#### Methods

The verification and validation project consisted of three major steps: (1) verification and comprehensive quality check of all Project Sonar data to assure its quality mirrors that of commercially available patient databases; (2) creation of an analytic dataset that merges disparate patient level data from electronic medical records, healthcare claims data, and patient reported outcomes; and (3) validation of CD and UC algorithms and Sonar risk scores. Assignment of patients into correct risk category was confirmed by verifying the elements of the three sub-scores (i.e., burden categories) that were important to the treatment algorithm and development of the overall risk score, and assuring that each element and sub-score were weighted appropriately. Then, the drivers for risk categorization were identified (i.e. the variables most commonly associated with patients moving to a higher risk category). Finally, convergent validity was assessed for the three sub-scores, risk categories, and Sonar scores by assessing the correlations between risk categories and other indicators of disease severity (e.g., health-related quality of life).

#### Results/Conclusions

Project Sonar provides a unique opportunity to combine electronic medical records, healthcare claims/resource utilization data, and patient reported outcomes to predict treatment failure and target appropriate therapy in a community-based setting. With the completion of this

comprehensive verification and validation process, the Project Sonar database provides a rich source of IBD patient data for understanding the natural course of IBD, identifying practice patterns, comparing treatment options and outcomes, and identifying potential therapeutic cost savings.

II. Project Sonar: Improvement in Patient Engagement Rates Using a Mobile Application Platform

Project Sonar: Improvement in Patient Engagement Rates Using a Cloud-based Platform

## Background

Project Sonar (PS) is a community-based registry and disease management program developed by the Illinois Gastroenterology Group (IGG) to improve clinical and economic outcomes in patients with Inflammatory Bowel Disease (IBD). PS integrates monthly patient-reported health-related quality of life (HRQoL) information using a subset of questions from the Crohn's Disease Activity Index (CDAI) sent via a Patient Portal (PP) producing a monthly 'Sonar Score'. These scores are then joined by clinical data fields delivered through electronic medical record derived Clinical Decision Support tools (CDS). This combined data is analyzed against payer provided-claims data to provide comprehensive, real-time information to physicians and patients on current symptoms and health status, as well as composite 'Sonar' scores. In an effort to improve portal-based patient response rates PS deployed the SonarMD Platform (SMDP), a cloud based platform developed by SonarMD, LLC which uses smartphone technology to improve patient engagement instead of a PP.

#### Methods

Patient surveys were developed using five questions derived from the Crohn's Disease Activity Index in an effort to obtain HRQoL scores. The sum of the values on these questions results in a Sonar Score (SS) which produces a quantifiable assessment of HRQoL. SSs are monitored for individual scores as well as the slope of change over time, which allows for the development of care management algorithms that drive interventions. The PP was used to send these surveys from January 2014 through May 2015. Due to an unacceptable PP response rate, the SMDP was deployed in June 2015. Patient response rates were compared for each of the two methods.

#### Results

The patient response rate for the PP averaged 27.6% over the 17 months of its use. Due to the structure of the PP, SSs needed to be individually calculated upon their receipt resulting in significant staff expense and a delay in patient feedback. The patient response rate for the SMDP was 66.27% for the three months it has been deployed, far exceeding the rate of the PP. Since the SMDP platform automatically calculates the SS at the time the patient answers the survey, patients receive immediate algorithm derived responses. Staff time is significantly reduced as a result.

#### Conclusion

Project Sonar provides a unique opportunity to combine electronic medical records, healthcare claims/resource utilization data, and patient reported outcomes to predict treatment failure and target appropriate therapy in a community-based setting. Since patient participation is critical to the success of PS, the cloud-based SMDP's superior performance improved the patient response rate over the patient portal from 27.6% to 60%. It also resulted in significant savings in staff time. More time of deployment will be necessary to confirm that these findings will stand the test of time.

III. Project Sonar: Validating a Cost Normalization Methodology in a Community-based Registry

TITLE: Project Sonar: Validating a Cost Normalization Methodology in a Community-Based Registry

**AUTHORS:** Kosinski, Lawrence<sup>1, 2</sup>; Sorensen, Michael <sup>2</sup>; Brill, Joel<sup>2, 3</sup>; Landsman-Blumberg, Pamela<sup>4</sup>; Turpin, Robin<sup>5</sup>; Baum, Charles<sup>5</sup>

#### **INSTITUTIONS (ALL):**

- 1. Illinois Gastroenterology Group, Elgin, IL, United States.
- 2. SonarMD, LLC, Elgin, IL, United States.
- 3. Predictive Health, Paradise Valley, AZ, United States.
- 4. Xcenda, LLC, Palm Harbor, FL, United States.
- 5. Takeda Pharmaceuticals USA, Inc, Deerfield, IL, United States.

#### **BACKGROUND**

- Project Sonar, a community-based registry and disease management program developed to improve clinical and economic outcomes in Inflammatory Bowel Disease.
- Project Sonar, uses a cloud-based platform combining health-related quality of life (HRQoL) information with clinical data delivered through electronic medical record derived Clinical Decision Support tools.
- These data fields are then combined with payer provided-claims data obtained from the Intensive Medical Home with Blue Cross Blue Shield of Illinois (BCBS-IL) database.

# **OBJECTIVES**

 Develop and validate a normalization methodology to mitigate the variation of cost data between actual payments made vs a normalized payment structure derived from Medicare Payment information to allow for meaningful assessment of Project Sonar's economic impact.

#### **METHODS**

#### **Patient Sample**

 Patients participating in Project Sonar and continuously enrolled in BCBS-IL from January 1, 2014 through September 30, 2015.

#### **Costing Method**

- Crohn's related claims-based payments were identified for each patient in the BCBS-IL medical claims with ICD-9-CM 555.X or select ICD-9-CM symptom codes.
- Claims-based payments were calculated and presented as total Crohn's-related payments and by type of service (i.e., infusible injection, diagnostic services, inpatient services, and physician services).
- All claims-based payments were adjusted to 2015 US dollars using the medical component of the Consumer Price Index

#### **Normalization Method**

 Normalized Crohn's-related payments were calculated using standardized provider payments as displayed in Table 1.

#### **Table 1. Factors to Normalize**

Service Type	Factors to Normalize
Physician Services	CPT Code Payment on 2015 Outpatient Prospective Payment System
Diagnostic Services	2015 Clinical Diagnostic Laboratory Fee Schedule
Infusible Biologics	2015 office based payment rates
Inpatient Hospital Payments	DRG Payment

- To remove bias from site of service all infusible biologics were normalized to office based infusion rate of \$85/unit compared to \$158/unit
- For inpatient Hospital Payments:
  - The DRG Payment was calculated using a base rate derived as the sum of the Operating Base Payment and the Capital Base Payment.
  - The base rate was then multiplied by the DRG Weight derived from the Medicare Severity Diagnosis-Related Groups Relative Weighting Factors.

#### **Analysis**

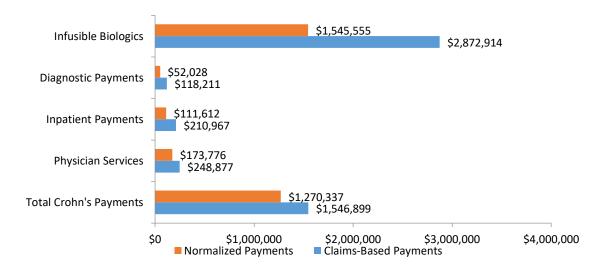
• We examined the absolute difference and percentage difference between actual and standardized payments for total Crohn's-related payments and by type of service.

#### **RESULTS**

#### **Sample Description**

 185 patients participating in Project Sonar and continuously enrolled in BCBS-IL were included in the analysis

Figure 1. Crohn's-Related Payments, Total and by Type of Service



- Normalized Crohn's –related payments are consistently lower than claims-based payments (see Figure 1), although the percentage difference varies by service type
  - o Total: 18%
  - o Physician services: 30%
  - o Inpatient services: 47%
  - Diagnostic services: 56%
  - Infusible biologics: 46%
- Diagnostic
- Inpatient
- Physician
- X% of infusions were administered in the hospital outpatient department which may contribute to the large difference in normalized payments compared to claims based payments

#### **LIMITATIONS**

- ICD-9-CM codes for Crohn's related symptoms were selected based on clinical opinion after review of a sample of medical claims for BCBS-IL Crohn's patients enrolled in Project Sonar and the published literature. Therefore, costs could be underestimated if relevant ICD-9-CM codes were omitted and overestimated if symptom claims included were related to alternative diagnoses.
- Claims data are collected for the purpose of billing, not research. Therefore, diagnoses may be coded incorrectly or under-coded, possibly introducing measurement error.

#### **CONCLUSIONS**

- Project Sonar represents a unique opportunity to manage care using the AGA Crohn's Care
   Pathway and analyze the results on payments.
- For meaningful comparison, it is essential that payments are normalized against Medicare Payments in order to mitigate the site of service differential in payment reporting.
- The normalization methodology presented has broad applicability for those seeking to analyze complex real-world clinical practice data and cost.

IV. Project Sonar Abstract of Distinction: Digestive Disease Week 2016

Project Sonar: Reduction in Cost of Care in an attributed cohort of patients with Crohn's Disease.

Lawrence Kosinski,<sup>1</sup> Michael Sorensen,<sup>1</sup> Joel V. Brill,<sup>2</sup> Pamela B Landsman-Blumberg,<sup>3</sup> Robin Turpin,<sup>4</sup> Charles Baum<sup>4</sup>

1. Sonar MD, LLC, Elgin, Illinois; 2. Predictive Health, LLC, Paradise Valley, Arizona; 3. Xcenda, LLC, Palm Harbor, Florida; 4. Takeda Pharmaceuticals U.S.A., Inc., Deerfield, Illinois.

Background: Project Sonar (PS), a joint venture between Illinois Gastroenterology Group and Blue Cross Blue Shield Illinois, is a community-based registry and disease management program developed to improve clinical and economic outcomes in Inflammatory Bowel Disease (IBD). PS integrates patient-reported symptoms and health-related quality of life information with clinical data delivered through electronic medical record derived Clinical Decision Support tools (CDS) using a cloud-based program developed by SonarMD, LLC. CDS tools are based on the American Gastroenterological Association's Crohn's Disease Care Pathway (CDCP) to determine treatment guidelines for Crohn's Disease (CD). Clinical data is combined with payer claims data to provide comprehensive, real-time information to physicians and patients on current symptoms and health status, as well as composite 'Sonar' scores. This study reports performance of Project Sonar in a subset of continuously enrolled CD patients.

Methods: 152 attributed patients with CD were continuously enrolled in PS between Jan 1, 2014 and Sept 30, 2015. The baseline period was Jan 1 through Nov 30, 2014, and the study period was the PS go-live of Dec 1, 2014 through Sept 30, 2015. Total Costs were corrected for the difference in time periods. CD-based claims were identified using ICD-9 555 codes plus additional codes identified as Crohn's-based due to their relationship with CD. Payments for physician and diagnostic services were normalized using a methodology based on Medicare payment rates; DRG payments for inpatient stays were adjusted to eliminate site of service differentials in payment rates.

#### Results

			Total Normalized			Emergency			
	Total Crohn's	Patient	Crohn's	Normalization	Inpatient	Room	Infusable	Injectable	
Crohn's Payments	Payments	Payment	Payments	Difference	Payments	Payments	Biologics	Biologics	<b>Total Biologics</b>
Pre-Period	\$2,118,308.65	\$ 13,936.24	\$ 1,932,069.37	\$ (186,239.28)	\$ 210,967.47	\$ 52,363.19	\$ 892,443.30	\$ 560,980.84	\$ 1,453,424.14
Study Period	\$1,884,758.63	\$ 12,399.73	\$ 1,741,326.02	\$ (143,432.62)	\$ 90,410.85	\$ 24,465.00	\$ 972,485.87	\$ 423,561.72	\$ 1,396,047.59
Difference	\$ (233,550.02)	\$ (1,536.51)	\$ (190,743.36)	\$ 42,806.66	\$ (120,556.62)	\$ (27,898.19)	\$ 80,042.57	\$ (137,419.12)	\$ (57,376.55)
Percentage Difference	-11.03%	-11.03%	-9.87%	-22.98%	-57.14%	-53.28%	8.97%	-24.50%	-3.95%

Findings: Total payments for PS patients with CD declined by 11.03% driven by > 50% declines in hospital and emergency room payments. Utilization of physician administered biologics rose 8.97% but total biologic costs declined 3.95% driven by a 24.5% reduction in the use of injectable biologics. Normalization of payments to eliminate site of service payment differentials resulted in a 9.87% savings in payments.

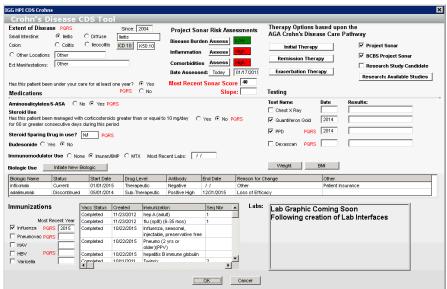
Conclusions: PS demonstrates value-based improvement in care for CD patients in a community-based setting through integration of clinical data, patient reported outcomes and healthcare claims/resource utilization data. Over 50% declines in hospital admissions and emergency room visits were achieved through CDS tools promoting adherence to AGA CDCP combined with intense patient engagement. PS represents an innovative model of population health likely applicable to other chronic conditions.

#### V. Guide to the Use of the Crohn's Disease CDS Tool

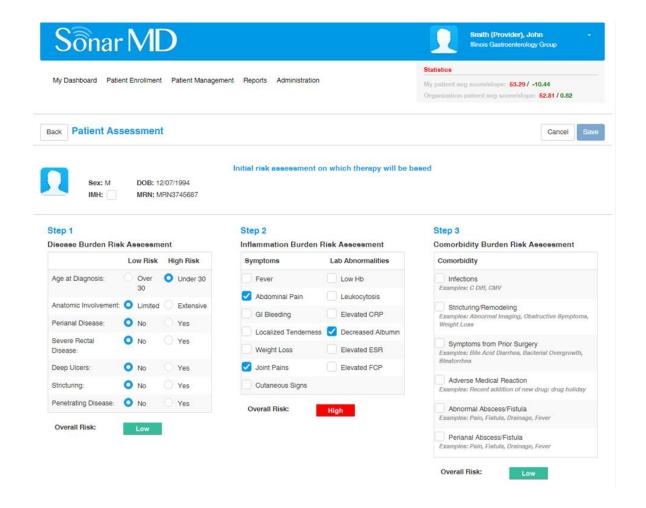
The use of CDS tools is critical to our success in the management of our patients with chronic disease. They also provide us an opportunity to bring together our PQRS requirements and serve as a platform for participation in research studies. Accordingly, the Project Sonar Physician Advisory Board, with the approval of the IGG Board of Managers, has decided to make the use of these CDS tools mandatory. This document will provide you clarity in how to enter data into this template.

The Crohn's Disease CDS Tool is a "Demographic" template and therefore only has to be populated only once. It will remain in its populated state from visit to visit and only requires updates. It will be launched automatically when you enter a chief complaint of Crohn's Disease.

The template has several sections as shown below:

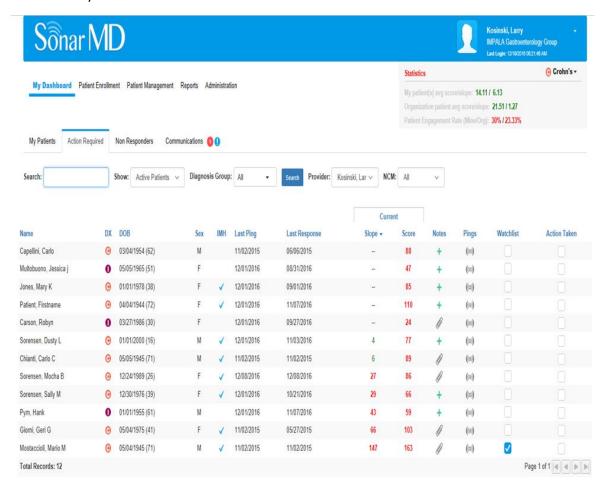


VI. AGA Crohn's Disease Care Pathway Risk Assessment
25 metrics are captured in three categories: Disease Burden, Inflammation Burden, and
Comorbidity Burden. This assessment is updated annually on each patient. SonarMD is
developing a mathematical model behind the relative strengths of each metric.
Currently due to the size of our sample population, we are not able to reach statistical
significance. The implementation of this APM on a national basis would provide the
necessary patient population.



## VII. SonarMD Nurse Care Manager Dashboard

The demo site shown below with fictitious patients demonstrates the user interface that the NCMs and Physicians use each month to monitor their patients. Patients are listed according to the assigned list of each NCM and Physician. Their raw Sonar Scores as well as the slope of their scores over time are listed with color coordination based upon algorithmic rules. The NCM or Physician can drill down on each one for further details. See VIII below.



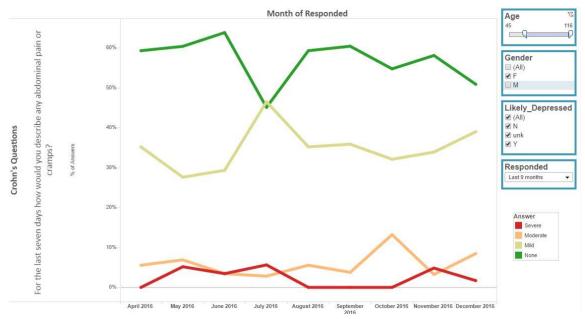
# VIII. SonarMD Patient Survey

This template allows the reviewer to drill down on individual surveys. Each patient receives the following questions every month via their device of choice. This template is an example of what the NCMs utilize to monitor the answers and scores.

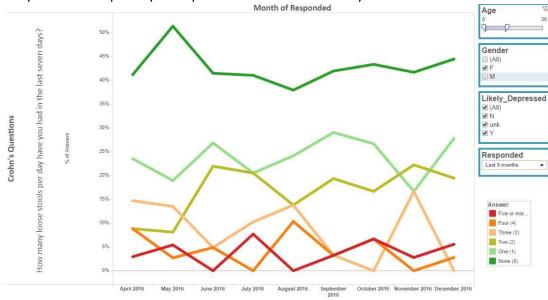
Date Sent Date Received	11/01/2016	09/28/2016 <b>~</b>	09/01/2016 99/07/2016
Survey Score:	57 Auto	41 Test new Suppleme	66 Auto
Question How many loose stools per day have you had in the last seven	One (1)	One (1)	Two (2)
days? For the last seven days how would you describe any abdominal pain or cramps?	Mild	Mild	Mild
Over the last seven days how would you describe your general well being?	Generally Well	Poor	Slightly Under
Select any of the symptoms you have had over the last seven days:	Eye Pain	Eye Pain	Eye Pain
Are you currently taking any medication for diarrhea?	Yes	No	Yes
Do you have any questions or comments for your care team?	Completed by M. Sorensen	Mike testing	Survey taken by M.Sorensen
Are you currently taking one of the following medications?	Entyvio		
Are you currently taking one of the following medications?		None of these	None of these

## IX. Examples of SonarMD Ping Reports

The report corresponds to the answers for the first question in the survey shown in the vertical axis. For the last seven days how would you describe any abdominal pain or cramps? The figure can be filtered by the items shown on the right side: age, gender, depression rating and by responder percentage.

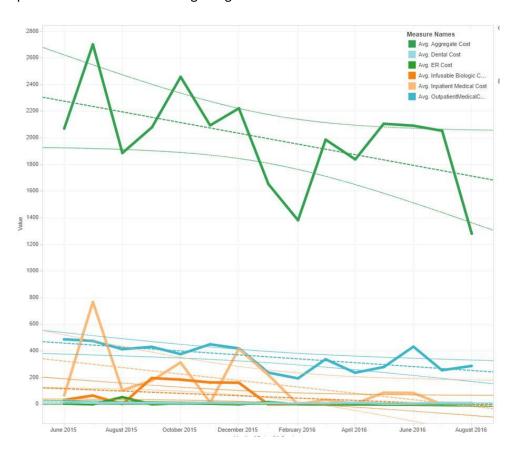


The following figure demonstrates the same findings for the second question: "How many loose stools per day have you had in the last seven days"



# X. SonarMD Cost Report

The following figure shows a stead fall in average aggregate cost of care over the time period of June 1st 2015 through August 31st 2016.



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

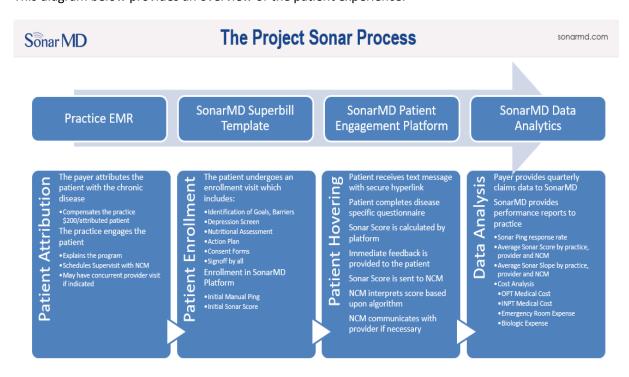
#### **Questions for Submitter**

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

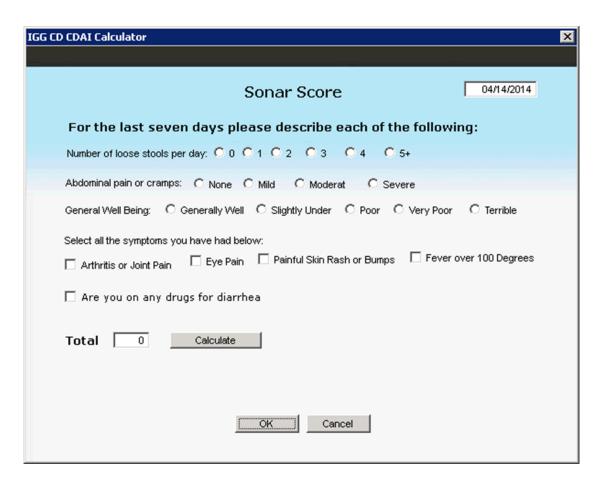
3. Project Sonar has been tested with the commercially insured population, which is different (e.g. age distribution) than the Medicare population. Is there evidence that Project Sonar can engage patients and is successful across different patient demographics, including the Medicare population?

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 IBD<sup>1</sup>. 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:

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



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?

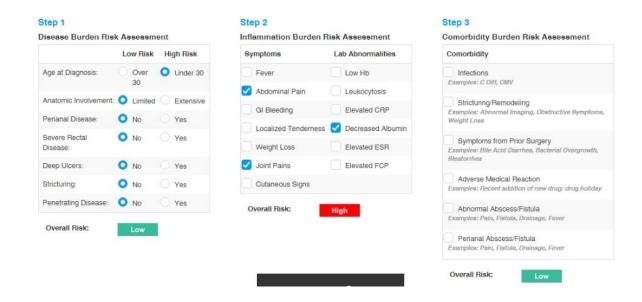
We are proposing a model that expands to address conditions in addition to Crohn's Disease. We believe that the patient characteristics in the CD population which we have uncovered can be advanced and expanded to other high beta chronic diseases. We define high beta diseases as those that are high cost 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?

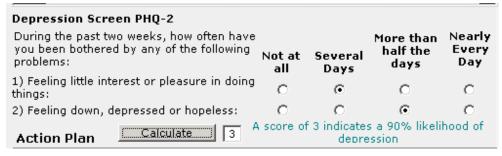
Coordination with the patient's primary care providers (PCPs) is critical. The platform is designed to feed information to any of the providers involved in the care of the patient. Critical to the management of the patient is a recognition of and establishing whom is the responsible provider, and how 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.



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



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.

#### **Descriptive Statistics**

=					
			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

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.

	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%	
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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%	

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 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:
  - o 10% discount if response rate is maintained over 60%
  - o 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
  - o 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:

- 1) 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:

- 1. 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.