DIGESTIVE HEALTH PHYSICIANS ASSOCIATION

Please Provide Responses to the Fields Below Electronically to be Accepted

Medicare Red Tape Relief Project
Submissions accepted by the Committee on Ways and Means, Subcommittee on Health

Date: August 25, 2017

Name of Submitting Organization: Digestive Health Physicians Association

Address for Submitting Organization: 12510 Prosperity Drive, Suite 200, Silver Spring, MD 20904

Name of Submitting Staff: Mr. Kevin Harlen, DHPA Executive Director

Submitting Staff Phone: 240-485-5201

Submitting Staff E-mail: Kevin.Harlen@capitaldigestivecare.com

Statutory___ Regulatory _XXX__

Please describe the submitting organization's interaction with the Medicare program:

The Digestive Health Physicians Association (DHPA) is the only national medical association that exclusively represents the voices of those gastroenterologists who have chosen to care for patients in the independent practice setting. DHPA has grown to include 75 member gastroenterology practices from 36 states in every region of the country. Our more than 1,700 physicians provide care to approximately 2.5 million patients annually in more than four million distinct patient encounters.

Medicare is a major payer for gastroenterology practices, yet the statutory and regulatory provisions governing physician self-referral law (the "Stark" law) that were created more than a generation ago in a strictly fee-for-service payment system are a major impediment to specialty practices delivery of high quality, coordinated care under the value-based payment structures created through the bi-partisan Medicare Access and CHIP Reauthorization Act. DHPA asks that Congress address statutory and regulatory concerns triggered by the Stark law that act as barriers to improving patient care in the Medicare program.

Short Description:

Streamline regulations to create a meaningful and transparent role for PTAC in designing and implementing specialty-focused APMs.

Summary:

DHPA believes implementation of Physician-Focused Payment Models ("PFPMs") is absolutely critical to the overall success of MACRA. In order to ensure that success, the

Physician-Focused Payment Model Technical Advisory Committee ("PTAC") needs to be given greater authority to design, develop and implement PFPMs.

Independent gastroenterology practices have been at the forefront of developing PFPMs for the benefit of Medicare beneficiaries. The first of those proposals, Project Sonar, 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."[1] The second proposal (which will be resubmitted to PTAC, in revised form, this Fall), the Comprehensive Colonoscopy Advanced Alternative Payment Model for Colorectal Screening, Diagnosis and Surveillance ("Colonoscopy Advanced APM"), is "a comprehensive prospective bundled payment advanced alternative payment model [designed] to more effectively manage patients who require colonoscopy for colorectal cancer screening and surveillance, for evaluation of a positive finding of on other CRC screening modalities as recommended by the US Preventive Services Task Force, and for other diagnostic purposes."[2] DHPA supports both proposals, because we believe that Project Sonar and the Colonoscopy Advanced APM are the types of innovative care models that will ensure high quality, cost-efficient care for Medicare beneficiaries.[3]

Unfortunately, CMS has refused to set deadlines on its obligation to review PTAC recommendations in a timely manner.[4] And, with the PTAC having reviewed only three of the

---

[1] See Project Sonar submitted by the Illinois Gastroenterology Group and SonarMD, LLC (Dec. 21, 2016), available at https://aspe.hhs.gov/system/files/pdf/253406/ProjectSonarSonarMD.pdf p. iv (last accessed Aug. 18, 2017).

[2] See Colonoscopy Advanced APM submitted by the Digestive Health Network, Inc. (Dec. 28, 2016), available at https://aspe.hhs.gov/system/files/pdf/253406/PFPM.pdf (last accessed Aug. 18, 2017).

[3] Public Comment from Digestive Health Physicians Association to Physician-Focused Payment Model Technical Advisory Committee (Jan. 20, 2017) re: Project Sonar Advanced APM ("DHPA Comment on Project Sonar"),available at https://aspe.hhs.gov/system/files/pdf/255731/ProjectSonarPublicComments.pdf (last accessed Aug. 18, 2017); Public Comment from Digestive Health Physicians Association to Physician-Focused Payment Model Technical Advisory Committee (Jan. 5, 2017) re: Colonoscopy Advanced APM, available at https://aspe.hhs.gov/system/files/pdf/255731/ComprehensiveColonoscopyAAPMPublicCommentsUpdated.pdf (last accessed Aug. 18, 2017) ("DHPA Comment on Colonoscopy Advanced APM").

[4] 81 Fed. Reg. 77008, 77492 (Nov. 4, 2016) ("We do not believe it would be reasonable to require that we adhere to a deadline in deciding whether to test a particular proposed PFPM. It is important for us to retain the flexibility to test APMs when we believe that it is the right time to do so, taking into account the other APMs we are currently testing, any potential design changes to the proposed PFPM, interactions with our other policies, and resource allocation.").

13 proposals submitted to date (one of the three being Project Sonar),[5] clinicians are left to wonder whether CMS will prioritize the conversion of models developed by the PTAC into MIPS APMs or Advanced APMs. The concern is even greater when factoring in the additional 17 Letters of Intent filed with PTAC,[6] which can be expected to result in more formal proposals being submitted with the reasonable expectation that they should be acted upon in a timely fashion. This backlog creates a missed opportunity, as the briefest of summaries of Project Sonar and the Colonoscopy Advanced APM demonstrate.

Project Sonar is a critically important Advanced APM for our physicians who are on the front lines diagnosing and caring for thousands of patients with Inflammatory Bowel Disease (IBD). The two variants of IBD—Crohn's Disease and Ulcerative Colitis—are among the most significant, chronic gastrointestinal conditions, affecting upwards of 1.5 million Americans.[7] The key to Project Sonar, which has been deployed, to date, with great success for patients with Crohn's disease, is the combined use of evidence-based medicine coordinated with proactive patient engagement. A Project Sonar Advanced APM will have great value on two levels—not only will it have a profound impact in care delivery for thousands of patients with Crohn's disease, but it can serve as a model for the expansion of Project Sonar and other chronic care management programs that physician specialists can employ for the benefit of their patients.[8] In its Report to the Secretary, PTAC recognized that "Project Sonar holds promise" and that "the potential benefits of the model justify moving forward with [limited-

[5] See "Reports to the Secretary," (voting to recommend Project Sonar submitted by the Illinois Gastroenterology Group and SonarMD, LLC and the ACS-Brandeis Advanced APM submitted by the American College of Surgeons for limited-scale testing and voting not to recommend the COPD and Asthma Monitoring project), available at https://aspe.hhs.gov/proposal-submissions-physician-focused-payment-model-technical-advisory-committee (last accessed Aug. 18, 2017)

[6] See "Proposal Submissions: Physician-Focused Payment Model Technical Advisory Committee," available at https://aspe.hhs.gov/proposal-submissions-physician-focused-payment-model-technical-advisory-committee (last reviewed Aug. 21, 2017).

[7] An analysis in the peer-reviewed literature estimates that annual, IBD-associated treatment costs in the United States are $6.3 billion ($3.6 billion for Crohn's disease, $2.7 billion for ulcerative colitis). See Kappelman, MD, et al., "Direct Health Care Costs of Crohn's Disease and Ulcerative Colitis in United States Children and Adults," Gastroenterology 2008 Dec; 135(6): 1907-1913, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2613430/, (last accessed Aug. 18, 2017).

[8] As we noted in our public comments supporting Project Sonar, there are four aspects of Project Sonar that make it a PFPM particularly worthy of implementation: (i) Project Sonar enables us to decrease the cost of care for our patients with Crohn's disease by decreasing the complication rate through better medical management; (ii) Project Sonar enables us to identify the high-risk patient with Crohn's disease before complications ensue; (iii) Project Sonar enables us to channel care of patients to those healthcare professionals in our practices who have the most knowledge, experience and expertise to address the specific patient's needs; and (iv) Project Sonar enables us to better engage our patients so that early warning signs can routinely be assessed even before the patients realize they need intervention. DHPA Comment on Project Sonar p. 2.

scale] testing."[9]

For its part, the Colonoscopy Advanced APM is a comprehensive, prospective bundled payment with retrospective reconciliation that will encourage practitioners from multiple specialties to collaborate and coordinate care across settings to more effectively manage patients who require colonoscopy for colorectal cancer (CRC) screening, diagnosis, and surveillance, and for other diagnostic purposes. As we noted in our public comments in support, given the critical nature of early CRC screening as a tool in fighting colon cancer, and the serious deficiencies in screening rates that continue to exist in eligible U.S. adults age 50 to 75, the Colonoscopy Advanced APM presents a perfect opportunity to close the gaps in CRC screening, improving detection of CRC at early stages, decreasing the rate of CRC, and improving survival for this disease.[10] Importantly, the Colonoscopy Advanced APM will also address a substantial problem with Medicare's current reimbursement scheme, which unnecessarily pays hospitals twice as much as independent ambulatory surgery centers for the facility fee in connection with identical colonoscopy procedures.

Despite the innovative delivery and payment models being developed and submitted for consideration to PTAC, to date, PTAC's recommendations are accorded no priority for review by CMS and the Agency has explicitly refused to place any deadline whatsoever on when it will review those PTAC-approved proposal.

Related Statute/Regulation:

81 Fed. Reg. 77492 in CY 2017 MACRA Final Rule discusses Physician-Focused Payment Models and the Physician-Focused Payment Model Technical Advisory Committee process for reviewing PFPM.

Proposed Solution:

We urge the development of metrics to ensure the success of PTAC, including:

1. Commit (i) to a 90-day period from date of submission for the PTAC to review and decide whether to approve a PFPM as an Advanced APM or MIPS APM, and

[9] See PTAC Comments and Recommendations to The Honorable Thomas E. Price, Secretary, U.S. Department of Health and Human Services, re: Project Sonar (May 31, 2017), available at https://aspe.hhs.gov/system/files/pdf/255906/SonarReportSecretary.pdf (last accessed Aug. 18, 2017).

[10] DHPA Comment on Colonoscopy Advanced APM p. 2.

a. (ii) to approve a certain number of PTAC-proposed PFPMs as Advanced APMs each year;

2. Provide clinicians with clearer guidance in their development of PFPM proposals by publishing relevant, objective benchmarks that will be used by PTAC and CMMI to approve submitted models;

3. Apply a rebuttable presumption that, at a minimum, CMS will adopt any PFPMs approved by PTAC as MIPS APMs.