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

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Statutory_XXX__ Regulatory___

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:

Reform of the Stark self-referral law and associated fraud and abuse laws to permit improved care coordination and facilitate participation in alternative payment models.

Summary:

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10, enacted April 16, 2015) replaced Medicare's sustainable growth rate formula with a new Quality

Payment Program. Under the new program, the Centers for Medicare & Medicaid Services (CMS) determines physician updates based on participation in either the Merit-based Incentive Payment System (MIPS) or Alternative Payment Models (APMs).

Both MIPS and APMs emphasize care coordination within medical group practices and often with hospitals and other providers across multiple sites of service. These new payment reforms incentivize physicians to provide care more efficiently while also improving patient outcomes.

However, the Medicare statute's physician self-referral prohibitions found in section 1877 of the Social Security Act (commonly known as the "Stark law") that were enacted nearly 30 years ago pose barriers to care coordination, because physician practices are prohibited from using revenue from "designated health services" in order to incentivize more efficient care delivery within their practices.[1] Many of the relevant exceptions under the Stark law prohibit payment arrangements that take into account in any manner the volume or value of referrals or other business generated by the parties.

As CMS recognized long ago, with respect to ACOs and the MSSP, these requirements under the Stark law serve as a barrier to the implementation of incentives for increased quality of care and decreased utilization. As such, CMS established waivers from the Stark law's prohibitions, as well as for the Anti-Kickback law's prohibitions, for ACOs participating in the MSSP.

DHPA is strongly committed to the success of the new payment paradigms offered under MACRA and is eager to assist GI practices across the country successfully participate in APMs and deliver better and more coordinated care. However, our ability to achieve these goals is hampered by the lack of protection under the Stark law for physicians seeking to participate in alternative payment models.

DHPA supports both Project Sonar and the Colonoscopy Advanced APM (like many other stakeholders), which will require waivers to the Stark law to implement successfully. Since those models have not yet been approved, our practices are unable to test them in "real world" clinical practice for the benefit of Medicare beneficiaries while we await CMS action. This inability to ensure that APMs can be tested with the Medicare population before approval and expediting the approval of models that have been recommended by PTAC is specifically addressed by the regulatory reforms described below.

Related Statute/Regulation:

Section 1877 of the Social Security Act and associated regulations pertaining to compensation, as well as providing waiver authority from anti-kickback, civil monetary penalties and Title XVIII of the Social Security Act as found in similar waiver authority set forth in section 1899(f) of the Social Security Act, 42 U.S.C. § 1395jjj(f).

[1] See generally 42 U.S.C. § 1395.

Proposed Solution:

DHPA and a coalition of 25 specialty physician organizations have been working closely with the Ways and Means Committee staff on legislation to modernize the Stark law by removing barriers to participation and care coordination in alternative payment models, and to encourage the Committee to advance that bill to enactment this year**.** Allowing such payment arrangements should do no harm to the original intent of the Stark law – to regulate improper incentives that could lead to increased utilization. The bill accomplishes this by amending the Stark law to:

(1) Facilitate physician group practice development and participation in alternative payment models by exempting "value and volume" from the fair market value standard.

(2) Empower HHS to provide the same waiver authority for all types of alternative payment models that have been provided to Medicare Shared Saving Program's accountable care organizations;

(3) Reform Stark's punitive and cumbersome strict liability standard to a more workable "knowing and willful" approach used under the civil monetary penalties law.

Specifically, the legislation would make four important reforms to the Stark law:

(a) Waivers to Promote Care Coordination in MACRA Programs

This subsection permits CMS to waive the Anti-Kickback Act, Civil Monetary Penalties and Stark law provisions that are barriers to participation in all types of alternative payment models. This waiver authority is similar to the current waiver authority set forth in section 1899jjj(f) of the Social Security Act to facilitate participation in the Medicare Shared Savings Program.

(b) Promotion of Care Coordination through Expansion of Administrative Authority to Provide Exceptions to Physician Ownership and Compensation Arrangement Prohibitions

This subsection gives CMS broader authority than under current law to create exceptions to the Stark law that do not pose a significant risk of program or patient abuse, including those that would promote care coordination, quality improvement or resource conservation. It also ensures that CMS will not interpret the Stark law to impose requirements (even under current exceptions) that could adversely affect physician care coordination in the Merit-based Incentive Payment System or participation in Alternative Payment Models under the Medicare program.

(c) Elimination of Volume or Value of Referrals in the Development and Operation of Alternative Payment Models

For arrangements entered into for the purpose of developing or operating an Alternative Payment Model (including, Advanced APMs, APMs approved by the Physician Technical Advisory Committee, MIPS APMs and other APMs specified by the Secretary) and that are in writing and signed by parties to the arrangement, items and services must be subject to fair market value except that they may not take into account volume or value. The arrangement must meet other requirements as the Secretary may impose by regulation as needed to protect against significant risk of program or patient abuse. This provision recognizes the protections needed for practices striving to qualify for any type of APM under a written agreement with the Secretary and for those operating approved APMs.

This reform is critical to the successful testing and operation of APMs, particularly those provided by physician specialty practices because a substantial portion of practice revenue is derived from designated health services, which are presently tightly regulated by the Stark statute. If practices cannot reward or penalize their physicians monetarily for abiding by best practices and exemplary treatment pathways, we have little ability to deliver more coordinated care that can improve health outcomes and restrain costs.

(d) Intentional Violations of Physician Self-Referral Prohibitions

Due to the fact that the Stark law is a strict liability statute, the health care industry has seen the application of significant fines for noncompliance that results from ministerial omissions, such as the failure to sign a lease renewal. In many instances, such technical violations result without knowledge or intent on the part of the participants. CMS has recognized the need for softening the Stark law's requirements around technical documentation noncompliance by expanding the acceptable evidence of what constitutes a written agreement.

This subsection limits the Stark law sanctions for physician compensation arrangements found to violate the Stark law to only those arrangements that trigger the civil penalty provisions of the Anti-Kickback Statute (which is a knowing and willful standard). Technical violations of the Stark law that do not otherwise trigger the civil penalty provisions of the Anti-Kickback Statute would not carry any penalties. Violations of the Stark law with respect to physician ownership interests would continue to be considered problematic and potentially abusive on a strict liability basis.