February 6, 2015

Submitted via: http://www.regulations.gov

Marilyn B. Tavenner, RN, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1461-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Medicare Shared Savings Program:
Accountable Care Organizations, [CMS-1461-P]

Dear Administrator Tavenner:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide comments on policies outlined in the Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACO) proposed rule. IDSA represents more than 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the area of infectious diseases (ID). The Society’s members focus on the epidemiology, diagnosis, investigation, prevention, and treatment of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious infections, including meningitis, pandemic influenza, pneumonia, tuberculosis, surgical infections, those with cancer or transplants who have life threatening infections caused by unusual or drug-resistant microorganisms, people living with HIV and AIDS, and new and emerging infections, such as Middle East Respiratory Syndrome (MERS), and Ebola virus disease.

IDSA members are committed to improving the quality and safety of patient care in a manner that aligns with the value-based principles of alternative payment models and that recognizes the changes towards more integrated health care delivery. The MSSP encompasses much of the effort that CMS has put forth to move towards a more value-based, integrated, accountable delivery of high quality health care for Medicare beneficiaries. We recognize the changes as set forth in this proposed rule are done in a spirit of improvement through evolution, applying lessons learned from the establishment of over 350 ACOs since the inception of the MSSP. Below we submit our comments in the hopes of contributing to the improvements by providing our perspective on the implications of the proposed changes.
General Comments on the MSSP and ACOs

Recently, Secretary Burwell announced that by 2016, 30% of all Medicare provider payments will be in alternative payment models (such as ACOs) and by 2018, 50% of all Medicare provider payments will be within such models.\(^1\) We appreciate the ambition to vigorously move to payment based on value, not volume. We also appreciate the complexity involved in starting up a program that provides guidance and appropriately measures accountable care organizations. We believe there is much work to be done to balance the ambition and the administrative complexity in order to best engage the provider community. Our two primary concerns with the ACO model as defined in the MSSP are as follows:

1. Governance that allows for fair representation of ACO participants and emphasizes appropriate distribution of shared savings achieved
2. Flexibility to participate in multiple ACOs

To provide context to our comments, we mention here that most of our members in clinical practice are employed within large multi-specialty practices affiliated with large academic medical centers or community hospital/health systems. However, we do have a significant portion of our members in clinical practice who practice as solo practitioners or in small, single specialty practices. Our first concern listed above applies to all of our members in clinical practice. The second concern applies mainly to the small and solo practicing specialists.

Composition of the Governing Body and Leadership & Management Structure

IDSA appreciates CMS’ efforts to provide clarity on issues related to ACO governance, leadership, and management. Specifically, we are supportive of the proposed expansion of the fiduciary duty owed to an ACO by its governing body to include the duty of loyalty. We feel that the proposed change to require, without exception, at least 75% control of the ACO’s governing body to be held by ACO participants is one that will promote more responsible governance and ensure loyalty to the overall ACO's interests. We appreciate CMS' reiteration of the statutory standard of having a "mechanism for shared governance" among ACO participants.

In addition, we ask that CMS develop guidance to help ACOs establish a shared savings distribution model that fosters a fair and sustainable shared savings distribution process. We agree that MSSP ACOs should have flexibility in determining what proportion of shared savings is appropriate for distribution among ACO participants and ACO providers/suppliers, and should be allowed to determine what portion of the savings should be reinvested in the ACO’s infrastructure. We do stress that the shared savings model should consider the contributions of each individual ACO provider/supplier and ACO participant when considering how to distribute the shared savings. Furthermore, we urge CMS to establish benchmarks to determine whether the ACOs shared savings distribution process is facilitating or limiting care coordination activities and access to specialty care.

CMS has proposed changes with respect to the Leadership and Management structure of ACOs pertaining to operations and clinical management as well as oversight of the quality assurance

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program. We are supportive of the flexibility that CMS would allow in its proposed changes with respect to the medical director requirement. Allowing a medical director that is not an ACO provider/supplier but yet is still familiar with the ACO’s organizational culture and clinical operations is reasonable. As well, we are supportive of the proposed change requiring a prospective ACO to submit documentation regarding the qualified health care professional responsible for an ACO's quality assurance and improvement program. We ask that CMS consider providing more guidance that describes suitable training, experience, and knowledge of how to run an effective quality assurance and improvement program. In our view, the qualified health care professional charged with the responsibility of running this program would be knowledgeable in population health management and effective care coordination across various sites-of-service. Furthermore, given the growing threat of antimicrobial resistance (AR), we feel that those in charge of an ACO’s quality assurance and improvement program should be trained and knowledgeable in infection control and prevention practices as well as have a thorough understanding of the benefits of antimicrobial stewardship. IDSA continually promotes awareness of the AR threat and, therefore, we feel that it should be a consideration in efforts to evolve the health care delivery system.

Assignment of Medicare FFS Beneficiaries: Consideration of Physician Specialties and Non-Physician Practitioners in the Assignment Process

Currently, CMS employs a two-step process to determine beneficiary assignment to ACOs. The first step focuses on physicians designated as General Practitioners, Family Practice, Internal Medicine, and Geriatric Medicine, (aka “primary care physicians” for purposes of MSSP). Any of these types of physicians who are ACO providers/suppliers and who provide the majority of the primary care services in a year to a Medicare beneficiary will have that beneficiary assigned to the ACO to which the provider belongs. If a beneficiary does not receive primary care services from a primary care physician in a given year, or the provider from which they received primary care services is not in an ACO, then the process of assigning the beneficiary moves to step two.

In step two, specialists who are ACO participants and who have provided “primary care services” (E/M visits) to the beneficiary will have that beneficiary assigned to the ACO to which the provider belongs. CMS has proposed that certain specialty providers should be exempt from the determination of specialty assignment. This is significant because providers that determine the assignment of beneficiaries to ACOs face exclusivity requirements that prohibit them from participating in more than one ACO. Therefore, providers whose primary care services do not factor into the beneficiary assignment determination process will be free to participate in multiple ACOs. IDSA has long advocated that ID specialists should be free to participate in multiple ACOs as, often times, they visit multiple hospitals and their clinical practice can span wide geographies. Thus, we respectfully request that Infectious Diseases (specialty code 44) be excluded from step 2 of the beneficiary assignment process in the MSSP final rule.

We feel it would be appropriate for CMS to add ID as well as other cognitive specialties to the list of excluded specialties as it would be consistent with CMS’ policy reflected in the implementation of the Primary Care Incentive Program (PCIP). Under this program, CMS pays an incentive payment of 10 percent of Medicare program payments to qualifying primary care physicians and certain non-physician practitioners (family medicine, geriatric medicine, pediatric
medicine, internal medicine, nurse practitioner, clinical nurse specialist, or physician assistant) who furnish specified primary care services (E/M visits). However, in the proposed MSSP rule, CMS states that, "As a general rule, for example, we expect that physicians with an internal medicine subspecialty would frequently be providing primary care to their patients." This appears to be an inconsistency in how CMS views providers of primary care services. Therefore, it would be seemingly appropriate for CMS to apply the distinction that exists in the PCIP to the development of the “excluded specialties” list for ACO beneficiary assignment or it should recognize internal medicine subspecialists under the PCIP. We feel that it is important that CMS ensure consistency across programs.

Furthermore, we ask that CMS provide clarity on how specialties that are excluded from the ACO beneficiary assignment process go about assigning TINs to multiple ACOs and how it will ensure that administrative errors are avoided. Should this proposed change be adopted in the final rule, we are concerned that solo practitioners and single specialty practices will encounter problems as it is discovered that their TINs are associated with multiple ACOs.

Finally, on the issue of including non-physician practitioners in determining ACO beneficiary assignment, we ask that CMS suspend consideration of this proposed change until the ability to distinguish the self-reported specialty codes that appear on claims for services provided by NPs, PAs, and CNSs is in place. Without the ability to distinguish the specialty indicated, services provided by these non-physician practitioners will ultimately trigger beneficiary assignment under Step 1, as CMS states, “inappropriately based on specialty care over true primary care.”

Billing and Payment for Telehealth Services

Currently, Medicare pays for telehealth services furnished by a physician or practitioner under certain conditions even though the physician or practitioner is not in the same location as the beneficiary. The telehealth services must be furnished to a beneficiary located in one of the eight types of originating sites specified under law.

IDSA is supportive of CMS’ proposal to allow waivers to ACOs with respect to how they employ telehealth services, relaxing requirements that pertain to the originating site. We understand CMS’ concern over possible abuse of the waiver and therefore, we are supportive of the proposed requirement that ACOs provide a written plan detailing how it would use the waiver to meet the clinical needs of its assigned beneficiaries. The practice of telemedicine, as a component of telehealth, varies widely in terms of its adoption across specialties and sites-of-service. Therefore, we propose that CMS follow-up with medical societies to discuss how they would apply telemedicine within the context of an ACO arrangement. IDSA stands ready to engage CMS in a discussion of how telemedicine can be used appropriately to benefit beneficiaries within ACOs.

Homebound Requirement Under the Home Health Benefit

Under current statute allowing for the Medicare home health benefit, a physician must certify (and recertify) that such services are or were required because the individual is or was "confined

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2 “What is telehealth? How is telehealth different from telemedicine?” Retrieved from http://www.healthit.gov/providers-professionals/faqs/what-telehealth-how-telehealth-different-telemedicine
to the home” and needs or needed skilled nursing care on an intermittent basis, or physical or speech therapy or has or had a continuing need for occupational therapy. In this proposed rule, CMS discusses this definition of home health services and opens the possibility of providing a waiver of this requirement within ACOs. CMS lays out the rationale that if a beneficiary is allowed to have home health care visits, even if the beneficiary is not considered home-bound, the beneficiary may avoid a hospital admission and thus, result in lower overall costs.

IDSA commends CMS for its willingness to explore this possibility and would welcome the opportunity to further discuss how Outpatient Parenteral Antimicrobial Therapy (OPAT), provided under the Medicare Home Health benefit, should be included under such waivers. OPAT has been shown to effectively treat patients with severe infection while avoiding hospitalizations and also effecting early discharge for patients who would otherwise be confined to the inpatient setting. Therefore, we are supportive of issuance of a waiver for ACOs contingent on home health agencies becoming ACO providers and of the requirement that ACOs provide detailed plans as to how the waiver will ensure the avoidance of abuse.

IDSA appreciates the opportunity to provide comments on the MSSP ACO proposed rule and recognizes CMS’ considerable efforts to improve the program to ensure future success. We look forward to further collaboration with CMS in pursuit of the program’s goals in a manner that effectively engages providers. Please feel free to direct any comments or questions to Andrés Rodríguez, IDSA’s Director of Practice and Payment Policy, at arodriguez@idsociety.org or at 703-408-4015.

Sincerely,

Stephen B. Calderwood, MD, FIDSA
President

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