October 28, 2016

Clinical News

CMS Releases Final Regulations on New Medicare Payment System; Hosts Session to Educate Providers

The Centers for Medicare and Medicaid Services (CMS) has released final regulations on how it plans to implement the new payment system called the Medicare Quality Payment Program (QPP). The QPP will begin on January 1, 2017, and is intended to restructure the way in which clinicians are compensated for the services they provide and marks a clear transition to value-based healthcare delivery. In the final rule, CMS has provided flexibility for clinicians who may not be ready to fully transition to the QPP on January 1, which was a primary recommendation in our comments on the Proposed Rule. This "pick your pace" approach will give clinicians until October 2, 2017 to begin participating in the program. Regardless of when you begin participating, performance data must be submitted to CMS by March 31, 2018.

This performance data will serve as the basis of 2019 payments which will be increased, decreased, or remain flat depending on the quality, resource use, improvement activities, and meaningful use of electronic health record technology that is reported by the practice. Clinicians must submit at least one quality measure, one improvement activity, or the five required Advancing Care Information (ACI) measures in order to avoid a four percent penalty in 2019. Clinicians may qualify for a small positive payment adjustment by reporting more than the minimum one patient for one quality measure, improvement activity, or five ACI measures for 90 consecutive days and earn a composite score above the threshold set by CMS. Clinicians will earn a moderate payment adjustment if they choose to report for the full year and earn a composite score above than the threshold.

Additional Information

Below please find a summary and explanation of the payment rule. For additional information, CMS is hosting a call to provide an overview of the MIPS and Advanced APM payment provisions. Physicians can register for the MLN Connects Call on November 15 from 1:30 to 3:00 PM ET.

CMS has also launched a QPP resource center to help clinicians navigate the new regulations and determine which measures and improvement activities are most meaningful for their practice. The Endocrine Society has also launched a new webpage designed to provide our members with a one-stop shop for resources to help with the transition to the new payment system. The recent Clinical Endocrinology Update meeting included a session that provided attendees with a comprehensive overview of MACRA based on the Proposed Rule.

Advanced Alternative Payment Models:

The QPP contains two tracks to provide clinicians with practice-centered options for participation. The first track allows groups who wish to take part in an Advanced Alternative Payment Model (APM) to receive a 5 percent incentive payment for their participation. In the Final Rule, CMS has eased the risk criteria for an APM to qualify as an Advanced APM in an effort to address concerns that many practices would be ineligible to participate in an existing Advanced APM. A final list of qualifying Advanced APMs will be released by January 1, 2017.

Merit-based Incentive Payment System:

For those clinicians that choose not to participate in an Advanced APM, the second track allows clinicians to earn a performance-based payment adjustment through the Merit-based Incentive Payment System (MIPS). Payment adjustment will be based on data reported in three categories in 2017: Quality, Improvement Activities (formerly knows as clinical practice improvement activities), and Advancing Care Information. Performance in each category will become part of the composite score for the clinician. Individual or group reporting will continue to be options. Final requirements the components are included below.

Quality (60 percent of composite score in 2017): In an effort to ease the reporting burden, CMS has reduced the number of measures that a clinician must submit from nine to six measures, one of which must be an outcome measure or high priority measure (if no relevant outcome measure exists). Clinicians may also choose to report a specialty measure set if available. Clinicians must report on a measure successfully for 50 percent of patients in 2017 and 60 percent of patients

in 2018. In the Proposed Rule, clinicians were required to report on 90 percent of patients or 80 percent for those physicians reporting via claims. A list of the measures and measure sets can be found on the QPP resource center.

Improvement Activities (15 percent of composite score in 2017): The Final Rule reduced the number of activities that clinicians must attest to in 2017. Clinicians must attest to two 20-point high weighted activities, four 10-point medium weighted activities, or any combination equaling 40 points. This is a reduction from the Proposed Rule that required three high weighted and six medium weighted activities for a total of 60 points. Small, rural, high professional shortage areas (HPSAs) and non-patient facing clinicians must report two medium weighted activities or one high-weighted activity. A list of the eligible Improvement Activities can be found on the QPP resource center.

Advancing Care Information: (25 percent of composite score in 2017): The ACI composite score is made up of the Base Score and Performance Score. Clinicians must report on all five required measures in the ACI Base Score (down from 11 measures in the Proposed Rule) in order to receive full credit, and up to an additional nine measures for the Performance Score. If a clinician fails to report on all four Base Score measures, they will not receive any of the points in the Base Score. Relevant measures can be found on the QPP resource center.

Clinicians can earn preferential scoring by reporting to public health and clinical data registries, and by using certified electronic health record technology (CEHRT) to complete activities in the Improvement Activities performance category. The Clinical Decision Support (CDS) and Computerized Physician Order Entry (CPOE) have been eliminated.

Cost: In a change from the Proposed Rule, CMS has determined that Cost information will not be factored into a practice's composite score for payment adjustment purposes in 2017. We voiced significant concerns about the patient attribution methodology in our Proposed Rule comments, as CMS expected to still be in the process of revising the methodology after the start of the 2017 reporting period. As accurate attribution of costs to a specific clinician will be a challenge, we recommended that this category by down weighted to 0 until an accurate attribution methodology is developed and reviewed.

For future years, CMS finalized 10 episode-based measures (a decrease from 41 in Proposed Rule), and the total per capita and Medicare Spending Per Beneficiary administrative claims cost measures that will be used to determine performance in the Cost category. CMS is also developing patient condition groups and patient relationship codes to assist with attribution. The Society

nominated two members, Dr Ron Harris and Dr. Illona Lorincz, to a CMS workgroup that is developing these codes. The episode-based measures can be found on page 601 of the Final Rule.

Support for Small and Rural Practices: We also urged CMS to provide support for small and rural practices to ease the transition for these practices that may have limited resources. There are a number of flexibilities in the Final Rule to help these practices, including exemptions for low volume practices, allowances for patient-centered medical homes, and increased technical assistance. CMS raised the low-volume threshold in the Final Rule to exempt clinicians from all performance reporting if they have less than $30,000 in annual Medicare revenue (increased from $10,000 in Proposed Rule) or 100 or fewer Part B-enrolled Medicare beneficiaries. CMS estimates that this will exempt 32.5 percent of eligible clinician from the program.

MACRA also provides $20 million each year for 5 years to fund training and education for Medicare clinicians in individual or small group practices of 15 clinicians or fewer and those working in underserved areas.

FDA Issues Recommendations for Improving the Use of Blood Glucose Monitors

The U.S. Food and Drug Administration has released two final guidance documents which provide recommendations to manufacturers on studies that should be included in premarket submissions for new blood glucose meters. This guidance is intended to improve new meters that come onto the market and make specific recommendations for those using these devices at home and for those using these devices in healthcare settings. The FDA expects that, when used together, these recommendations can improve the accuracy and safe use of blood glucose meters and improve outcomes for patients with diabetes.

Questions on the guidance documents can be directed to the Division of Industry and Consumer Education in the Center for Devices and Radiological Health at 301-796-7100 or dice@fda.hhs.gov. FDA will also be holding a webinar on Monday, November 21, from 11:00am to 12:30pm ET to discuss and to answer questions about these documents. The Endocrine Society has been engaged with the FDA on issues related to inaccurate blood glucose meters and is currently reviewing the final guidance documents. Additional information will be provided in a future issue of *Endocrine Insider* if areas of concerns are identified.

Labeling Changes for Testosterone Products Approved by FDA

The Food and Drug Administration (FDA) has approved class-wide labeling changes for all prescription testosterone products, adding a new Warning and updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS).

The new Warning will alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse. In addition to the new Warning, all testosterone labeling has been revised to include information in the Abuse and Dependence section about adverse outcomes reported in association with abuse and dependence of testosterone/AAS, and information in the Warning and Precautions section advising prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

The full MedWatch safety alert can be found on the FDA website.

National Diabetes Education Program Releases Online Guide for School Personnel

The NIDDK's National Diabetes Education Program has released the 2016 update of their school guide, "Helping the Student with Diabetes Succeed: A Guide for School Personnel". The guide, originally published in 2010, serves as a resource for school personnel and administrators to better support students with diabetes. According to recent estimates, over 23,000 youths are diagnosed with type 1 and type 2 diabetes each year, and the NDEP has found that students are better able to manage their diabetes when they are in a supportive school environment.

In addition to discussing diabetes management plans, staff training, and school responsibilities under federal law, the new guide features information about:

- diabetes equipment and supplies for blood glucose monitoring and administering insulin
- meal planning and carbohydrate counting
- effective diabetes management for children with type 2 diabetes
- psychosocial issues affecting students with diabetes

The Endocrine Society is among the 200 partner organizations that supported this effort.

Research News

Endocrine Society Members Elected to the National Academy of Medicine

The National Academy of Medicine (NAM, formerly the Institute of Medicine), was established in 1970 to address "critical issues in health, science, medicine, and related policy." In 2016, the NAM elected 70 new domestic and 9 international members, in recognition of major contributions to the advancement of medical sciences, health care, and public health. Newly elected members of the NAM include Endocrine Society members Roger D. Cone, Ph.D., Hugh S. Taylor, M.D., Cheryl Lyn Walker, Ph.D., and Donald P. McDonnell, Ph.D.

The Academy has addressed many issues of importance to Endocrine Society members, including testosterone replacement therapy in men, Medicare coverage of routine thyroid screening, and contraceptive research and development. The Society is encouraged by the election of Endocrine Society members to the NAM. We extend our congratulations to Dr. Cone, Dr. Taylor, Dr. Walker, and Dr McDonnell, and look forward to the impactful work that they will contribute to as members of the Academy.

New Policy Alters NICHD Research Funding Strategies

Recently, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) announced that they would slightly modify their approach to funding grants to enhance flexibility and better address scientific and public health priorities. In previous years, NICHD used a strict "payline" approach, where grant applications were funded according to a fixed cutoff point based on grant review scores, the institute budget, and the total number of applications received. Moving forward, for the R01, R03, R13, R15, and R21 grant mechanisms, NICHD will emphasize funding in research gaps and scientific priorities informed by the NICHD Scientific Vision and portfolio analysis. The Endocrine Society contributed to the development of the Scientific Vision, providing comments and recommendations on several of the broad scientific areas highlighted by the NICHD.

We encourage members to examine the NICHD branch websites for more information on research areas that will be emphasized in funding decisions. Note that NICHD will "continue to welcome, encourage, and support investigator-initiated applications that help advance our mission goals" according to the NICHD mission.

NIEHS Announces FOA to Study Mixture Effects

On October 19, the National Institute of Environmental Health Sciences (NIEHS) released a Funding Opportunity Announcement (FOA) through the R01 grant mechanism on Powering Research through Innovative Methods for Mixtures in Epidemiology (PRIME). The FOA was issued with the intent of stimulating "the development of innovative statistical, data science, or other quantitative approaches to studying the health effects of complex chemical mixtures in environmental epidemiology." The Endocrine Society has advocated for greater consideration of mixture effects in regulatory decisions involving endocrine-disrupting chemicals and we are encouraged that NIEHS will stimulate targeted research in this important area through the FOA.

Take Action: We encourage Endocrine Society members who conduct toxicological research on EDCs or other chemicals to examine the full FOA at the NIH Grants Guide.

For questions regarding articles listed in *Endocrine Insider* or information on advocacy and policy activities within the Endocrine Society, contact the Government & Public Affairs department:

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