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June 27, 2016

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Administrator Slavitt:

The Louisiana Rural Health Association (LRHA) is pleased to respond to the Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models proposed rule. We appreciate your continued commitment to the needs of the 62 million Americans residing in rural and underserved areas, and look forward to our continued collaboration to improve health care access and quality.

The LRHA is a non-profit membership organization with more than 400 members throughout Louisiana that provides leadership on rural health issues. Our membership includes nearly every component of rural Louisiana's health care infrastructure, including rural community hospitals, critical access hospitals, Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs) doctors, nurses and patients. We work to improve rural Louisiana's health needs through advocacy, communications, and education.

We are generally supportive of the proposed rule; however, we have concerns around the fact that it would inherently penalize small medical practices. The small practices throughout rural America have fewer resources to invest in care infrastructure and fewer patients and providers to smooth out any outliers in the data. We respectfully request CMS carefully consider the impacts of these programs on rural, safety net, and independent practices to maximize the benefit for the patients and to accurately reward high performing providers.

We appreciate that the rule moves away from a disjointed and disparate data reporting and provider scoring programs, and generally improves CMS' approach to paying providers by rewarding high-value care. In particular, we support the Clinical Practice Improvement Activities section, which is flexibly structured and rewards providers for the high-value care activities such as expanding practice access, coordinating care for patients and investing in population health. Importantly, it rewards reform-minded providers who are already engaged in transformation work with substantial credit for their participation in health reform initiatives such as the Medicare Shared Savings Program, Practice Transformation Networks and certified patient-centered medical homes.

Our primary concerns with the proposed rule center around the fact that it would inherently penalize small medical practices – which by their very nature have fewer resources to invest in care infrastructure – and around the structure of the Merit Based Incentive Payment System Resource Utilization domain, which will have the unintended consequence of inhibiting referrals to, and care partnerships with, rural and safety net providers due to their unavoidably higher cost structure. The following is a summary of our specific policy recommendations. We focus our attention on the Merit-Based Incentive Payment System (MIPS) portion of the rule because that is where the vast majority of providers, including our clients, will participate within the Quality Payment Program (QPP).

Performance Comparisons Should Occur Between Equivalent Cohorts

Actuarial estimates predict that the Merit-Based Incentive Payment System (MIPS) will penalize 72% percent of medical practices with 24 or fewer providers, 87% of solo practitioners, 69.9% of practices with 2-9 eligible clinicians, and 59.4% of practices with 10-24 eligible clinicians (see table 64 on p. 28376 of the proposed rule). We do not doubt the veracity of the table. Our experience with smaller primary care practices shows they have fallen behind larger practices in

terms of implementation of the basic programs of prevention, wellness, care coordination, patient health management and electronic health records. Furthermore, these practices generally do not have the same amount of practice with data collection and analytics and quality reporting.

Large practices have been actively involved in the type of population health management programs for some time that small practices are just beginning to implement today. They are active participants in Medicare Advantage programs, which cover 1/3 of beneficiaries, and are accustomed to wellness visits, care coordination and comprehensive diagnosis coding of their patients to accurately reflect their chronic conditions. In contrast, most independent providers do not have those processes in place and still believe that it is morally wrong for them to record more than the “reason for visit” diagnosis on a claim, causing their patients HCC scores to be significantly below average. This problem was pointed out in MedPAC’s 2012 report on rural and is proven again by our data. Although it is widely published in peer-reviewed research that rural patients are sicker and poorer than the rest of the country, of our 23 rural ACOs, six have HCC scores below 1.0.

CMS has wisely focused on providing technical support for small and rural practices, which will narrow the gap between small and large practices over the next five years. In order to avoid punishing providers that are making the effort to adopt the new models of care, we propose that practices with 15 or fewer providers and those with 16 or more providers be divided into two distinct comparison groups. For future years, this cohort distinction could be modified based upon a statistical analysis to ensure practices are being compared with a peer group based defined by their statistical ability to perform equally well under MIPS. CMS could then compare similar-sized provider groups to one another, and calculate Hierarchical Condition Category scores and MIPS percentiles within each of the 2 distinct cohorts. This approach will promote a more rational comparison, and may avoid levying penalties on providers simply by virtue of their small practice size. This will account for the differences in resources and care management development of the two groups, incentivize both groups to improve and still identify those who are not making a reasonable effort to improve patient care.

LRHA Applauds the Inclusion of Rural Providers, While Encouraging Special Considerations for Those That Have Not Previously Participated in PQRS, VM, or MU.

Rural providers including Rural Health Clinics and other paid through alternative payment mechanisms have been excluded from previous programs. NRHA believes that non-participation in CMS quality improvement programs by rural providers deprives many rural residents of easily accessible information about provider performance, prevents many rural providers from earning payment incentives that are available to non-rural providers, possibly hinders implementation of comprehensive quality measurement efforts on behalf of rural residents, and potentially signals that rural providers cannot provide high-quality care. However, those providers without the experience and infrastructure to participate in these programs are at a disadvantage in a program based on comparison with peers. Therefore, NRHA encourages special considerations for those that have not participated in these programs, allowing a phased approach for full participation and protecting safety net providers from downside risk, similar to the CMS recommendations for small practices.

LRHA Urges CMS to Ensure Measures are Appropriate for Low Volume and Rural Providers.

CMS should adhere to the recommendations in “Performance measurement for rural low-volume provider: Final report by the NQF Rural Health Committee” dated September 14, 2015, which strongly recommends that rural providers are not exempt from this program. This report was created pursuant to HHS requesting the National Quality Forum to convene a multi-stakeholder Committee to identify challenges in healthcare performance measurement for rural providers and to make recommendations for mitigating these challenges, particularly in the context of CMS pay-for-performance programs. The need to create rural relevant measures does not mean the creation of separate measures for rural. Rural providers are often general practitioners that participate in a vast array of practice activities based on the need of their community, and dependent on the needs and resources available to the community. Core measures must be applicable to these primary care practices and measure selection must address the low case volume challenge, facilitate fair comparisons for rural providers, address areas of high risk for patients, support local access to care, address actionable activities for rural providers, be evidence-based, address areas where there is opportunity for improvement, be suitable for use in internal quality improvement efforts, require feasibility for data collection by rural providers, exclude measures that have unintended consequences for rural patients, be suitable for use in particular programs, align with other programs, support providing better care, healthier

people/healthy communities, and affordability. These requirements are not unique to rural, however, the challenges experience by rural providers must be considered when identifying both core and optional measures.

Many rural hospitals and clinician practices tend to be small, and these often have limited time, staff, and finances available for quality improvement activities, including data collection, management, analysis, reporting, and improvement. In many rural areas, few individuals have the specialized technological skills (e.g., ability to use EHRs or registries for measurement calculation/improvement) and/or quality improvement skills to use measurement results to drive improvements in care. Lack of financial resources also impacts ability to invest in HIT infrastructure and in quality improvement initiatives. Finally, those who serve in small hospitals and practices often have multiple, disparate responsibilities (e.g., direct patient care, business and operational responsibilities, etc.) that compete with quality improvement activities. However, it is possible to develop measures that do not penalize rural providers for the realities of rural practice. Multiple options exist for responding to the issue of low volume, including virtual groups, longer data collection time frames, and continuous variables.

LRHA is disappointed CMS did not include virtual groups in the proposed rule. The option to participate in virtual groups is an important tool for overcoming low volumes. Virtual groups should be as flexible as possible with few restrictions on who may participate, how many providers can be included, or how the groups must be set up. Providers are best positioned to determine how the groups should be structured based on the needs and resources available to the group. However, LRHA supports restrictions requiring all providers practicing under the same tax identification number (TIN) to be included in the same group. However, participating in virtual groups is not appropriate for all practitioners and should not be required of any practitioner even if their patient volume is insufficient for statistical analysis. For these practitioners the option of a longer time horizon, for example two years instead of one, may provide a sufficient sample size to analyze.

Another alternative is measures constructed using continuous variables. Measuring an aspect of care using a continuous variable rather than a binary variable may require a smaller sample size to detect meaningful differences between providers. Examples would be assessing the time until a medication is given rather than just whether or not a medication was given or measuring the

number of preventive services received rather than whether or not preventive services were received. Note, however, that care should be taken when considering such measures for rural providers (particularly timing measures), as such measures would be sensitive to outliers and because the environmental context could potentially invalidate comparisons between providers.

LRHA Encourages Minimization of the Burden of Data Collection and Timely Feedback to Providers.

Data collection is particularly burdensome for rural providers, either because small rural providers may not have the staff needed to collect data (e.g., for measures that require laborious abstraction from medical records) or because they may not have the resources (financial, staff expertise, etc.) to invest in or maximize use of sophisticated HIT systems that would facilitate calculating and reporting of quality measures. LRHA recommended that HHS work to develop standardized processes so that data that are used for various purposes would have to be reported by providers only once. Note that this recommendation can be operationalized only if there is alignment of the measure sets for the various purposes. Additionally, claims data already held by CMS should be utilized without additional input required from providers whenever possible.

Currently performance results used in CMS improvement programs may be 2 years or more out of date (e.g., data used in 2015 programs reflect care provided in 2013 or earlier). Such long look-back periods hinder receipt of rewards for more recent improvements in care. LRHA supports quicker and broader access to performance scores and “feedback reports” such as those provided as part of the Physician Feedback of Quality Resource and Use Reports (QRURs)/Value-Based Payment Modifier program (for clinicians) and the Medicare Shared Savings Program (for ACOs) and to Medicare data for quality improvement purposes. This sort of data allow for the identification of patients in a service area, as well as the types, locations, sources, and, sometimes, costs of care provided to patients. This kind of data should be provided to all providers as quickly as possible in order to improve the care coordination for patients, reduce the overall cost to Medicare, and drive overall improvement efforts.

LRHA Encourages Inclusion Rural-relevant Sociodemographic Factors in Risk Adjustment.

Statistics indicate that those living in rural areas may be more disadvantaged overall than those in urban or suburban areas, particularly with respect to sociodemographic factors or social determinants of health: health status and behaviors, and access to the healthcare delivery system.

For example, people in rural areas are more likely than others to have lower incomes, lower educational attainment, higher unemployment rates, and higher rates of poverty. According to data from the *2014 Update of the Rural-Urban Chartbook*, those in rural areas are, in general, more likely to be older (i.e., age 65 and above). Rural residents also are more likely to engage in certain riskier health behaviors (e.g., smoking among adolescents and adults; leisure-time physical inactivity) and have higher overall mortality in all age categories (i.e., children and young adults, working-age adults, and those 65 and older), compared to those in other geographic areas. Healthcare provider shortages, as well as limited availability of other resources such as technological expertise and transportation networks in rural areas, also affect how care is delivered (e.g., the need to transfer high-acuity patients to other facilities for specialty care). Moreover, many rural providers face challenges in quality measurement and associated accountability efforts because of low patient volume, which can impact the reliability, validity, and utility of performance metrics.

Considerations of cost and volume must take into account the factors unique to rural providers. Congress provides cost based reimbursement in rural settings in recognition of additional cost of providing low volume services. It is important that any value metrics examining costs do not penalize low volume rural providers for the inherently higher costs of providing essential, yet low volume services. Any measures of value should instead ensure providers are rewarded for providing the best value care in a given circumstance.

Currently, CMS adjusts calculations of rural costs for Value-Based payments to a wage-adjusted PPS rate for CAH inpatient and outpatient services, but does not similarly adjust rural costs of swing beds and rural health clinic visits. This policy penalizes low-volume rural providers and may have the unintended consequence of diverting patients from their primary care provider or preventing them from recovering in their community surrounded by family and friends. CMS should consistently apply normalization of rural costs to PPS rates to avoid unintended consequences that may further destabilize the rural delivery system and threaten access to care.

LRHA Supports the Voluntary Reporting of MIPS Data by Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) and Voluntary Listing on Physician Compare So Long as the Data is Adjusted to Reflect the Patients' Sociodemographic Risk Factors.

We caution CMS to not make assumptions about all RHCs based off of the voluntarily reported MIPS information. Early data will be potentially problematic due to the differences in the documentation and coding at RHCs and FQHCs, as well as technical issues in properly calculating aspects of the MIPS score (such as resource use). Since the system is not designed with these unique provider types in mind it is important that providers have the ability to begin to participate voluntarily without the potential detrimental effect of reporting information on physician compare without the express voluntary agreement of the provider after the opportunity to review their data. However, this voluntary reporting is an import step to improve MIPS in the future and to allow greater reporting by FQHCs and RHCs and the dissemination of comparable quality and value scores within physician compare.

LRHA further urges CMS to work with the Health Resources and Services Administration (HRSA) to harmonize their quality reporting requirements for FQHCs and RHCs with the MIPS program. This will lessen the administrative burden on providers and encourage reporting of quality and value metrics that are comparable. This harmonization does not require an identical system, and would continue to allow each to measure quality specific to the goals of the system, however, harmonizing would encourage reporting of comparable data with less administrative burden for providers.

While LRHA is Supportive of Voluntary Reporting by FQHCs and RHCs, We request that FWHCs and RHCs are not Subject to MIPS for the Small Number of Claims that are Submitted Under the Physician Fee Schedule.

While we support reporting for physicians practicing outside of the RHC or FQHC setting, we do not support the requiring reporting for physicians based on their practice within the RHC or FQHC. While the vast majority of services are reimbursed under the FQHC or RHC specific fee schedules, there are a few covered services – such as the technical components of certain lab tests and x-rays – which FQHCs and RHCs are required to bill under the PFS, using the name of the individual provider. Thus, even “typical” FQHC and RHC providers – meaning those who work exclusively at FQHCs or RHCs providing Medicare-covered primary care services to FQHC or RHC patients – submit some PFS bills.

LRHA supports the creation of a low-volume exception, but we are concerned that the exception to MIPS for providers that bill under the PFS for less than \$10,000 and 100 patients over the

course of a year will not properly exclude providers working in the FQHC and RHC setting as was intended. While many would be excluded under this criteria, some centers with a high percentage of Medicare patients would likely exceed the 100 patient threshold over the course of a year since this amounts to only 2 Medicare patients a week. LRHA is concerned that the time, effort and cost the FQHC or RHC must dedicate to getting a good MIPS CPS score would likely outweigh the rewards of a positive MIPS adjustment on this small portion of RHC or FQHC revenue. To alleviate this concern, LRHA recommends that the threshold be revised to an either/or standard (i.e., providers are exempted if they have less than either 100 patients or \$10,000 in fee schedule claims.) Alternatively, CMS could state that fee service claims for non-specialty services provided by FQHC or RHCs providers to FQHC or RHC patients are not counted when determining eligibility for the low-volume threshold.

LRHA urges a fix for Method II Critical Access Hospitals for MIPS Reporting.

Method II CAH participation in PQRS did not work as planned and the same issues will affect the QPP. Method II CAHs bill clinic visits on Medicare Part A (excluded from attribution) and inpatient and Skilled Nursing Facilities visits on Part B. The vast majority of patients attributed to Method II CAHs are institutionalized, causing them to appear to have much higher costs and lower quality than the average.

Issues may occur in QPP attribution when any portion of the services rendered by eligible professionals are excluded from Medicare's claims data database. CAHs that bill under Method II face these issues because CAHs that bill under Method II only see a small portion of their services reported on the CMS-1500 claim form and reimbursement under Medicare Part B. These services would include hospital inpatient, swing bed, nursing home, psychiatric and rehabilitation inpatient, and hospital outpatient services rendered in non-CAH settings. Services rendered for outpatients in the CAH setting (i.e. provider based clinic, observation, emergency room, surgery, etc.) are reported on the CMS-1450 (UB-04) form and are reimbursed through Part A and are exempt from the QPP. This results in beneficiaries who are less acute and low cost to the Medicare program (those seen in clinic settings and those who have avoided inpatient and post-acute care settings) being excluded in the QPP attribution, with only potentially high cost beneficiaries being counted. Therefore, while a CAH-based eligible professional may have a substantial portion of his or her patient population in a low-cost category, the methodology of PQRS attribution could still easily result in the eligible professional being reported as high cost.

In order to diminish this data disparity CMS should include all ambulatory physician services delivered in Method II CAHs in the PQRS attribution. For Method II claims, this would involve scrubbing outpatient claims for services reported with professional revenue codes (96X, 97X and 98X) that are matched up with the applicable CPT codes.

LRHA is disappointed with the limited definition of Advanced APM. This limitation means rural providers, for whom the operational risk of participating in an APM is more than nominal risk, are essentially excluded from participation in APMs.

Many rural providers operate on a relatively thin financial margin, with little room to absorb even temporary payment reductions without concomitant reductions in staff and/or services. Additionally, RHCs and CHCs, as well as many CAHs and small rural hospitals and clinician practices operate in federally- or state-defined shortage areas (e.g., Health Professional Shortage Areas or Medically Underserved Areas) and may be considered part of the nation's healthcare safety net. For these rural safety net providers, CMS should consider the operational risk of participation in an APM. The costs associated with participating including care coordination, training, new hires, costs associated with additional IT, etc. are more than nominal for a provider with a razor thin margin. Even without additional monetary risk these providers risk losing their business and their communities losing necessary access to care. Requiring any additional express risk makes rural providers ineligible for participation in EAPMs, an outcome at clear odds with the congressional intent of the law to expand their use and participation.

LRHA encourages CMS to reconsider requiring down side risk for those providers qualified as PCMH, but the requirements for PCMH certification are not clear. We urge CMS to develop a rural-appropriate PCMH model that accounts for the differences of provider shortages, access, resources and specialty care in rural areas, or to eliminate the requirement for rural providers to take risk in APMs.

For rural providers it is essential that the amount at risk requirements take into account the thin profit margins of the practice. Where the requirements for "nominal risk" exceed the profit margins of the practice, rural providers are unable to participate or risk losing their ability to remain in business. This leaves the practitioner with the choice of being excluded from APM participation at a time when CMS is attempting to increase the market share of APMs, further expanding the urban rural divide in health care and exacerbating the fact that the available APMs

are not designed to succeed in the rural practice setting. Alternatively, the practitioner is risking the viability of their practice on comparative metrics that CMS's own analysis show disadvantages small providers. The result will potentially further erode access to care in rural America.

We are particularly concern with the exclusion of Track 1 ACOs from Advanced ACO status. A provider participating in an ACO is investing resources into the ACO. Requiring simultaneous participation in MIPS and the Track 1 ACO is an additional burden that will decrease participation in ACOs in the future. Track 1 was created as an opportunity for providers to transition to ACO participation. This process involves a great deal of investment of time and money, as well as a steep learning curve. This exclusion with erode future participation in APMs in rural America by increasing the already high cost of participation, especially in the early years of participation. Furthermore, it is critical that CMS extend the 5% APM participation bonus for rural providers that do not bill under the Physician Fee Schedule, such as Rural Health Clinics. Rural providers desperately need this additional funding to offset some of the costs of APM participation. Finally, the exclusion of ACO track one from the definition of Advanced APM will potentially discourage providers from participating in an ACO since they will need to develop the infrastructure for MIPS participation as well as for the ACO tracking at a greater cost than the practice could absorb.

LRHA applauds the inclusion of technical assistance (TA) to small and rural, especially those located in health professional shortage areas. LRHA encourages CMS to continue to work with stakeholders to develop the TA as the specifics of MIPS and EAPMs are developed.

It is important that the TA utilizes lessons learned from other programs, such as the Transformation of Clinical Practice Initiative (TCPI) and the Regional Extension Center (REC) programs. Unlike RECs, TCPI gives providers a choice of grantees, where available. This allows grantees to specialize the type and method of assistance and to ensure that grantees are providing the TA providers need. This will be particularly important as different providers will have different needs in navigating MIPS and the transition to participation in an APM. In order to provide as much value to the providers as possible, LRHA urges the Federal Office of Rural Health Policy (FORHP) be given oversight in selecting and managing the technical assistance contract. FORHP has extensive background and experience in administering technical assistance

grants like this and is aware of the challenges and circumstances associated with rural health delivery.

Special focus should be given to those that have not previously participated in PQRS, MV, or MU, especially those that were not previously eligible for participation such as RHCs. These providers will require additional assistance in setting up the basics of participation. Participation in TA should be allowed over a longer time frame as such practices may only truly know what TA they need after initial experiences with participation. Such special consideration should also be given to providers making, or considering, the transition to participation in an APM. The TA provided through this program should be in line with, and consider other assistance already available (e.g., through the Quality Improvement Organization program under CMS, the Flex program under HRSA, etc.) to avoid duplication of efforts and ensure rural provider receive the sufficient assistance to facilitate successful participation. LRHA recommends such resources be aligned across HHS to support rural providers more efficiently and effectively. Such assistance will be particularly critical for those that are (or will be) new to quality measure reporting and/or to small providers who do not have sufficient staff expertise for measurement and improvement activities.

The focus on the majority of technical assistance should be on prevention and wellness, and care coordination services, structured data entry -and the use of claims data, EHR data mining and appropriate coding to ensure rural patients have accurate HCC scores. The TA should be in line with a wide range of IT capabilities, and may be required to include assistance in selecting or upgrading IT components and ensuring providers are using program-compatible browsers and software. TA may also be useful in disseminating best practices and effectiveness research for practices necessary to success in MIPS or APMs such as care coordination to ensure providers are able to modify their practice to provide services that deliver value to patients without undue cost to the provider and Medicare.

In order to ensure rural challenges are properly considered throughout the process, LRHA urges the creation of a Rural Affinity Group (RAG) at the direction of the Health Care Payment Learning and Action Network, under MITRE's CMS Alliance to Modernize Health Care (CAMH) Federally Funded Research and Development Center (FFRDC) contract with

CMS. This RAG would establish a work plan, convene stakeholders and recommend delivery and payment system reforms for demonstration to CMMI.

Thank you for the chance to offer a response on the implementation of MACRA. We respectfully request CMS to carefully consider the impacts of these programs on rural, safety net, and independent providers to maximize the benefit for the patients and to accurately reward high performing providers.

Sincerely,

A handwritten signature in cursive script that reads "Stacy Fontenot".

Stacy Fontenot
Executive Director
Louisiana Rural Health Association