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September 6, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

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

Re: (CMS–1693–P) Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and health professionals, appreciates the opportunity to respond to the *Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019*. We welcome the chance to share our concerns about the impacts these proposals will have on our ability to provide quality care to the 50 million Americans living with rheumatic diseases.

Rheumatologists provide ongoing care for Medicare beneficiaries with complex chronic and acute conditions that require specialized expertise. Rheumatologists and rheumatology physician assistants/nurse practitioners provide face-to-face, primarily non-procedure-based care, and serve patients with serious conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other inflammatory arthritides, vasculitis, systemic lupus erythematosus, and multiple other debilitating diseases. Early and appropriate treatment by rheumatologists and rheumatology professionals can control disease activity and prevent or slow disease progression, improve patient outcomes, and reduce the need for costly downstream procedures and care compared to care provided solely by primary care providers.

Executive Summary

Overall, the ACR is encouraged to see CMS working to better achieve transparency, flexibility, program simplification, and innovation with regard to reporting requirements, and evaluation and management (E/M) visit codes. We appreciate the emphasis on allowing practitioners greater flexibility to exercise their clinical judgment in documentation, so that they can focus on what is clinically relevant and medically necessary for the beneficiary. Such improvements are necessary to ensure rheumatology practices, especially small practices and those serving rural areas, are able to continue providing high-quality care to a growing Medicare patient population. Though we are appreciative of the efforts on the part of CMS, there are several problematic areas we would like to see CMS address. Please find our specific comments in the subsequent sections.

I. Provisions of the Proposed Rule for PFS

Determination of Practice Expense (PE) Relative Value Units (RVUs)

CMS worked with a contractor to conduct a research study to update the PFS direct PE inputs for supply and equipment pricing for CY 2019 and is proposing to adopt the updated direct PE input prices for supplies and equipment. CMS also proposes to phase in the use of the new direct PE input pricing over a 4-year period beginning in 2019. Unfortunately, the large shift on the direct practice expense will have significant fluctuations in the PE RVUS for approximately 27 key rheumatology procedures, such as 96372 therapeutic injections and 96401 drug administration injection or 76881 diagnostic ultrasound. These price reductions are grossly inappropriate and do not reflect the direct practice expense for supplies and equipment in rheumatology practices. Even with the recommended phase-in approach, the substantial shift in reimbursement will cause a devastating blow to rheumatology practices nationwide. There is a flaw in the methodology used to create the new model of codes that made changes in the indirect practice cost and caused the reduction of the PE RVU's. There is no transparency or explanation from the Agency on how that methodology was used. The ACR supports CMS's approach to reviewing the American Medical Association-Relative Value Scale Update Committee (RUC) recommendations and relying on RUC-recommended values as well as input from all stakeholders.

Potentially Misvalued Services under the PFS

Each year, CMS reviews and recommends a list of potentially misvalued codes for the AMA Relative Value Update Committee to review and make possible adjustments through surveys and comments from specialty societies. Since 2006, the RUC along with CMS has identified approximately 2,386 services through the AMA's various screening process which has resulted in $5 billion to be redistributed to the Medicare Physician Payment Schedule. This process has worked to identify codes that have been misvalued over the years. The ACR supports the work

of the AMA RUC and encourages CMS to seek stakeholder input along with the AMA in identifying potentially misvalued codes in future rulemaking.

Evaluation & Management (E/M) Visits

In the 2019 Medicare Physician Fee Schedule CMS is proposing to simplify E/M coding by condensing the CPT codes 99202-99205, codes that cover new patient office visits levels two through five, into a single payment of $135. Additionally, CMS proposes condensing CPT codes 99212-99215, the established patient office visits levels two through five, into a single payment of $93. CMS also proposes new rules that would decrease documentation requirements for patient history and exam by focusing on interval history since the last patient exam., These new rules are intended to save physicians time by not requiring them to re-enter information into the medical record but instead allowing them to simply review and verify certain information entered by ancillary staff or beneficiaries.

While we are pleased to see a focus on reducing physician burden by simplifying documentation requirements, we have serious concerns about the changes to evaluation and management (E/M) codes that result in cuts in reimbursement to cognitive specialists for the complex services they provide. CMS is proposing to reimburse doctors for all office visits equally regardless of the complexity of the patient's condition. CMS states that it has seen increased coding of higher-level visits and believes that eliminating the distinction in payment between visit levels 2 through 5 would reduce the need to audit against the visit levels, and therefore would provide immediate relief from the burden of documentation. The ACR believes the proposed cuts to cognitive specialty E/M services that are inherently more complex than those for generally provided for less complex problems. These cuts under value the complex but high value, nonprocedural care provided by rheumatologists and ultimately would severely impair access to cognitive care and worsen the rheumatology workforce shortage.

Additionally, we are skeptical that this proposal will simplify the reporting burden on providers in the Quality Payment Program. As proposed, the new plan proposes several "add-on" codes that would likely prevent reductions in audits or documentation burdens. On balance, the proposed benefits (a reduced burden of 51 hours/year per doctor, or less than 1 hour per week), are insufficient to offset the proposed cuts to reimbursement. For example, if a physician sees around 100 patients a week, this translates to under 40 seconds per patient, which is not a benefit that outweighs the proposed reduction in reimbursement. By CMS estimates this proposal will result in a 7% cut to rheumatology practices and in the best case 3% after accounting for the specialty add-on payment. These proposed cuts in physician reimbursement will be magnified by a multiple of 2 to 5 after fixed business overhead costs are paid. Further, this proposal does not address tort reform and therefore cannot meaningfully reduce the current need for documentation protecting physicians from frivolous litigation.

Further, complex patients require documentation to track physicians' medical reasoning that simpler cases do not, independent of billing concerns.

CMS has asked for comments on other documentation systems that could be used in conjunction with the current 1995 and 1997 guidelines. First, we suggest allowing providers to document and bill visits based on the level of medical decision making. It is important to understand that patient visits are unpredictable due to many different circumstances at the time of service. Medical decision making plays an important role in managing complex care and includes the rheumatologist's thought process on the presenting problems, risks, and how to utilize diagnostic tests. Second, the time and intensity required to see a patient with a rheumatic disease is dependent on varying characteristics that include comorbidities/underlying disease, other medical factors, and even social factors that increase the complexity of medical decision making, all of which need to be documented in the patient's record.

Overall, the ACR believes these cuts will reduce Medicare patients' access to care. Not distinguishing the care of patients with simple problems to those with complex conditions could deter physicians from seeing complex patients. If CMS moves forward with this policy change it would also exacerbate physician workforce issues, discouraging young physicians from entering specialties that provide complex care. We believe it does not make sense to equate diagnosing and treating a patient with cancer, rheumatoid arthritis, or ALS to a patient with the common cold. This proposal could also financially incentivize "cherry picking" where some offices only accept less-complex referrals and avoid sicker, and consequently more vulnerable patients. In order to maintain financially viable practices, physicians will be forced into one of several undesirable options:

- Spending less time with complex patients,
- Limiting the number of Medicare patients seen, or
- Scheduling numerous shorter visits to address all of the patient's concerns.

E/M Proposal Methodology

We are also concerned that CMS provided only minimal high-level estimates of the cumulative impact of most of these proposals on different physician specialties with no elaboration or sharing of the methodology. We encourage CMS to discuss how expected utilization for new add-on codes or other key factors was estimated. We believe a flaw in CMS methodology includes evaluating the impact on specialties at a macro level, without evaluating the impact on subspecialties or certain providers that may be more significantly affected by the proposal, such as rheumatologists who see patients in office settings (rather than in facilities) or those who practice in academic medical centers and primarily specialize in complex cases. The ACR has

been unable to replicate the numbers in Table 22 of the proposed rule. We ask that CMS share the methodology used so that we may fully understand the impacts to Rheumatology.

CMS further proposes a prolonged add-on code, but information about the utilization of the new proposed prolong service code is glaringly absent from CMS' impact analysis. We understand this exclusion may have been necessary because CMS did not provide robust guidance on how it anticipates utilization of this code to occur. CMS officials have mentioned in stakeholder meetings that the addition of this code would help to off-set the negative impact to some providers however, we cannot support a proposal that provides no clear details as to which specialties CMS assumes will be most likely to utilize the prolonged services add-on code, how frequently CMS expects it will reported, and the impact to specialties. Details regarding the use of the new add-on codes are vague, with little guidance for practices to implement and use correctly in such a short space of time without proper coding education.

Although we appreciate and commend the good intentions behind this proposal, including the reduction of paperwork and administrative burden, we urge CMS to not move forward with the current proposal and instead work closely with physicians and all stakeholders to identify alternative approaches that would accomplish CMS' goals, while ensuring that physicians are reimbursed appropriately according to the level of care required by each individual patient's condition. In addition, the timeline to implement such a drastic change will cause unintended consequences on EHRs, practice management systems and patient flow in practices.

Multiple Procedure Reduction Proposals

In addition to the E/M cuts, CMS is compounding the payment challenges facing rheumatology practices in their proposal to further reduce reimbursement for procedural services by 50 percent. This added reduction to essential therapeutic services is an excessive, unjustified reduction in reimbursement which will only exacerbate the current shortages in clinical care and quality outcomes.

Using the surgical MPPR as a template, CMS is proposing to reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier-25. The medical community and CMS have worked for several years to remove any overlap in the clinical labor time and practice expense for procedures commonly performed during the same encounter as an office visit. Therefore, the proposal would result in an excessive, unjustified reduction in reimbursement because the overlap in clinical labor time and practice expense has already been accounted for in the valuation of these services. CMS worked with the AMA Practice Expense committee for the past two+ years to remove any duplication of clinical staff time and direct practice expense from

procedures billed 50% or more with an E/M service. These refinements were accepted during those time periods.

We do not find this proposal appropriate. Again, the medical community has worked for several years to remove any overlap in the clinical labor time and practice expense of visits and same day procedures. Second, we are very concerned that this proposal will result in patients being asked to return on a different day for minor procedures (e.g., injections, joint aspirations, treatment of actinic keratosis), a situation that could also reduce the quality of care and increase copayments for patients.

Recommendations

Conservatively, the ACR recommends CMS continue with the proposal to provide documentation relief, but delay the payment elements while relevant stakeholders have a chance to research, discuss, and come to a consensus on the most appropriate way forward.

Alternatively, if CMS is insistent on moving forward with the E/M changes as proposed in January 2019, we urge CMS to rescind the idea of applying MPPR to E/M with a modifier 25 procedure; and instead **model or implement E/M payment reform that creates only neutral or positive payment updates for E/M based specialties and maintains the incentive to manage complex patients**. We understand that budget neutrality will require compensatory reimbursement shifts elsewhere in the fee schedule, but we are confident CMS can find an equitable solution that would not create a winners and losers scenario.

Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-based Payments

The rule is proposing that, effective January 1, 2019, WAC-based payments for new Part B drugs during the period first quarter of sales when ASP is unavailable, the drug payment add-on would be 3 percent in place of the 6 percent add-on that is currently being used. If this proposal is finalized, CMS will also update Manual provisions in order to permit Medicare Administrative Contractors to use an add-on percentage of up to 3 percent, rather than 6 percent, when utilizing WAC for pricing new drugs.

We appreciate that the proposed rule does clarify that the change in reimbursement would not apply to new biosimilars, whose reimbursement would remain at the drug's WAC plus 6% of the reference drug's ASP. In addition, reimbursement for established drugs whose WAC is below ASP would continue to be reimbursed at WAC plus 6%.

II. Other Provisions of the Proposed Rule

Clinical Laboratory Fee Schedule

CMS is seeking public comments on alternative approaches for defining an applicable laboratory and is particularly interested in receiving comments from the physician community in regards to the administrative burden and relief associated with revisions to the low expenditure threshold.

We are pleased to see that the Centers for Medicare and Medicaid Services (CMS) is working to update existing CLIA regulations that have not been updated in decades. The ACR believes some of these regulations are overly burdensome for providers and create barriers to timely, high quality care for their patients. We reiterate our comments from [*CMS-3326-NC] Requests for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under Clinical Laboratory Improvement Amendments of 1988 (CLIA).*

Currently, only laboratories that are CLIA certified level 2 and 3 are permitted to perform (and bill) for synovial fluid crystalline analysis. All rheumatologists receive fellowship level training to perform synovial fluid crystal analysis. This point of care test allows for rapid and cost effective evaluation of patients with crystalline arthritis and reduces unnecessary and costly additional testing to include advanced imaging procedures. A common example of the value of permitting rheumatologists to perform and bill for this procedure comes from a consult ACR President, Dr. David Daikh conducted this week. A complex care patient with diabetes, peripheral vascular disease, chronic kidney disease and history of gout presented with a warm swollen ankle the day before a scheduled vascular surgery. Aspiration of the joint did not produce a sufficient volume of material to send to the CLIA certified laboratory. However, expression of a small amount of material contained within in the needle used for the procedure onto a microscope slide yielded numerous gout crystals indicating an acute gout attack. This procedure prevented a hospital admission, a course of antibiotics and delay of the patient's scheduled surgery. Successful performance of this procedure and analysis is beyond the scope of CLIA certification and requirements. Unfortunately, the current CLIA certification requirements are unduly burdensome and prohibit the routine performance of this test in the appropriate clinical setting.

While CMS is reviewing and updating requirements for CLIA personnel and testing, the ACR recommends CMS create a special category of waived tests that would include the synovial fluid analysis when performed by a rheumatologist for care of their own patients. Creating this option would exempt a provider performing any CMS designated "waived tests" from burdensome CLIA level 2 and 3 requirements. No such category exists now, but there are other

clear examples of bedside tests in addition to synovial fluid analysis that should be considered (e.g., microscopic urinalysis by nephrologists and urologists, KOH preps of skin scrapings by dermatologists, etc.). Second, although there is no special category of waived tests, there is a list published by CMS entitled "Provider-performed Microscopy Procedures". We would ask that the synovial fluid analysis is included on this list if it would allow rheumatologists to perform crystal analysis in the clinical setting without undue administrative burden.

We urge CMS to downgrade or change the synovial fluid analysis from a 'high complexity' test to a 'provider-performed microscopy' procedure as is currently designated for urine dipstick and KOH prep, which would do away with the overly burdensome requirement for certification. To our knowledge, in order to perform these tests most facilities must pass evaluations that are sent via mail annually, and full lab certification is not required. Rheumatologists could meet a similar requirement in order to complete the synovial fluid analysis in their clinic. The full lab certification that is required currently is harming patient care and increasing burdens to the system.

III. CY 2019 Updates to the Quality Payment Program

Small Practice Bonus

CMS is proposing to retain a small practice bonus under MIPS by moving it to the quality performance category. We believe this would reduce the small practice bonuses to a negligible amount that does not truly help small practices. We request to maintain the bonus at 5% of the final score.

MIPS Exclusion Criteria

To be excluded from MIPS, clinicians or groups would need to meet one of the following three criteria: have ≤ $90K in Part B allowed charges for covered professional services, provide care to ≤ 200 beneficiaries, or provide ≤ 200 covered professional services under the Physician Fee Schedule (PFS). In the CY 2018 Quality Payment Program final rule (82 FR 53589), CMS proposed the option to opt-in to MIPS participation if clinicians might otherwise be excluded under the low volume. We urge CMS to explore ways to make benefits of the program apparent to a physician if they would like to opt-in. The ACR supports flexibility for excluded eligible clinicians to opt into the MIPS program in future years. As the program becomes increasingly operational and greater clarity makes it easier to comply, these excluded eligible clinicians are in the best position to determine the timing of the transition to compliance.

Cost Category

CMS is proposing to weight the cost performance category at 15 percent for the 2021 MIPS payment year. We urge CMS to not continue to increase the weights of categories that are outside of provider control at the expense of the Quality Category, which is the largest category that can be controlled by providers. Additionally, CMS maintains that a full calendar year performance period for the quality and cost performance categories will be less confusing for MIPS eligible clinicians. We advocate that CMS should pick the best 90 days in the Cost Category and not an entire year.

We urge CMS to exclude Part B medication costs from the cost performance category or at least include both Part D and Part B costs for a fair comparison. The calculation of resource use (i.e., costs) as currently proposed includes medication costs from Part B, but not Part D, which would result in inaccurate MIPS scoring. The ACR continues to advocate for minimizing this inaccuracy.

Performance Category

We also encourage CMS to continue its 2018 PI Performance Category policy to enable more EHRs and providers alike more time to upgrade to this standard. Maintaining the bonus for 2015 CERHT use would be less disruptive in the short term and incentivize compliance in the long-term. Alternatively, CMS could also allow for an exemption for the 2015 CERHT requirement if a provider is utilizing a QCDR for submission or is a small practice.

Qualified Clinical Data Registries (QCDR) Measures and Scoring

CMS believes that bonus points for high priority measures for all collection types may no longer be needed, and as a result, intend to consider in future rulemaking whether to modify the scoring policy to no longer offer high priority bonus points after the 2021 MIPS payment year. The ACR believes CMS should maintain high priority bonuses for QCDR submissions only; this would incentivize the use of QCDRs and would allow additional data to be collected for the program outside of the minimum 6 measures. We also believe CMS should maintain end-to-end bonus points for QCDRs to further incentivize their use and to offset the cost imposed by most EHRs to onboard with a QCDR.

Although CMS has established a policy to account for scoring in circumstances when the same measure is collected via multiple collection types, CMS anticipates that this will be a rare circumstance and does not encourage clinicians to submit the same measure collected via multiple collection types. We encourage CMS to allow for multiple submission types and calculate the best possible score for providers. This would reward providers, especially small practices, who are attempting to meet the spirit of the program. Moreover, if a provider switches practices mid-year, this will cut down on confusion if CMS accepts multiple

submissions to a provider's NPI. There is still great confusion on how providers should report if they are not at the same practice location in a given performance year.

We encourage CMS to provide physicians with more credit for participating in specialty clinical data registries under MIPS. Participation in the ACR RISE® Registry (Rheumatology Informatics System for Effectiveness), means rheumatologists are meaningfully using electronic health records to improve patient care, outcomes and practice efficiency. ACR strongly urges CMS to increase incentives for physicians to participate in clinical data registries by providing full PI credit for participation.

Finally, we believe that, in order to further the development of meaningful specialty-specific measures, CMS should support the protection of the extensive resources and intellectual property and that go into measure development, especially for QCDR measures when an organization goes through the rigorous process of development, collaboration with relevant external stakeholders and endorsement. Allowing duplicative measure concepts at a later time to go forward in the MIPS program fosters confusion among physicians and competition among QCDRs, rather than collaboration. The ACR feels strongly that organizations will not be able to continue to invest in advancing meaningful quality measures if their measure concepts are able to be appropriated with superficial changes and then supported by CMS.

Alternative Payment Models (APMs)

The ACR appreciates the desire of the agency to encourage development of physician-focused APMs, and we hope that CMS will make it easier for Physician Focused APMs to achieve "advanced" status by reducing nominal risk. The current nominal risk criterion makes it difficult for smaller practices to attempt the APM track. Smaller groups engaged in Physician Focused APMs should not be held to the same degree of nominal risk as large organizations such as ACOs. We also recommend that CMS lower the payment and patient count thresholds for Physician Focused APMs to allow "qualifying participant" status to be more achievable for smaller practices. We feel this would encourage more small practices to pursue Physician Focused APMs. We also continue to urge CMS to allow the set-up cost of physician-focused APMs to serve as the financial risk, at least for interim basis.

IV. Requests for Information

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

The ACR supports policies that will help improve the electronic health systems interoperability, which will be key in taking a comprehensive information sharing approach. We strongly support

interoperability of electronic health records, prevention of "data blocking" and other measures to streamline information sharing for clinicians and use of qualified registries. We support CMS's goal of encouraging interoperability of EHRs and information exchange, but our clinicians have experienced significant hurdles in their attempts to participate. We ask that CMS continue to evaluate the requirements to comply to ensure they are not too rigid or take the form of an "all or nothing approach." In addition to many interoperability issues beyond our control, compliance requires a significant investment in time and resources. We urge CMS to offer clinicians a flexible standard while interoperability is pursued.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

CMS is seeking information from the public regarding barriers preventing providers and suppliers from informing patients of their out-of-pocket costs; what changes are needed to support greater transparency around patient obligations for their out of pocket costs; what can be done to better inform patients of these obligations; and what role providers of health care services and suppliers should play in this initiative. The ACR supports policy that will provide beneficiaries with clear information about cost sharing and lower-cost alternatives. We believe utilization management processes should also be transparent in addition to information about cost sharing and lower cost alternatives.

We urge HHS to institute policies that require pharmaceutical companies, pharmacy benefit managers, and insurers to be more transparent about their payment practices, including transparency around the true cost of prescription drugs, as a necessary means of evaluating the efficacy of drug pricing and utilization policies. Policies requiring more uniformity or standardization in the ways that these companies structure and convey their rebate, pricing, and formulary programs, including uniform definitions for terms used in disclosures by specifying what constitutes a rebate, discount, fee, and amount received from a manufacturer is needed.

The ACR proposes the inclusion of automated line items on pharmacy receipts that detail the amount of savings, or additional cost, that a patient incurs by utilizing their pharmacy benefit plan. These line items would function much like the savings line items on grocery store receipts that inform customers how much is saved in a shopping trip by using coupons and taking advantage of in-store deals. Instead, these line items would tell patients in concrete terms how much their pharmacy benefit is saving them. Conversely, it would also tell them how much additional it is costing them if the copay required by utilizing their pharmacy benefit is higher than the cash price of a drug. This automated disclosure would provide transparency at the point of sale and empower patients to make more informed choices about purchasing medications, as well insurance policies.

The ACR is dedicated to ensuring that rheumatologists and rheumatology health professionals have the resources they need to work with CMS and provide patients with high-quality care. We believe that for CMS, clinicians, and patients to all achieve their objectives, payment programs must be designed to reflect the way practices treat patients. The American College of Rheumatology appreciates the work CMS does and the opportunity to respond to this proposed rule. We look forward to being a resource to you and to working with the agency. Please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs, at kamodeo@rheumatology.org or (202) 210-1797 if you have questions or if we can be of assistance.

Sincerely,

David I. Daikh, MD, PhD
President, American College of Rheumatology