



September 11, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: [CMS-1676-P] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program

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 2018 Proposed Rule*. We welcome the chance to share our concerns on the impact 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 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 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.

I. Background & Summary

Overall, the ACR is encouraged to see CMS seeking robust stakeholder input to better achieve transparency, flexibility, program simplification, and innovation with regards to reporting requirements, evaluation and management (E/M) visit codes, relative value units (RVUs), appropriate use criteria (AUC), and payment for biosimilar biological products. 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. However, there are several problematic areas we would like to see CMS address; please find our specific comments in the subsequent sections.

II. Payment Provisions

Changes in Valuation for Specific Services

Practice Expense Inputs

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. However, we are concerned about the magnitude of the reimbursement reduction to the current procedural terminology (CPT) code 76881. Musculoskeletal ultrasound is a vital, emerging, economic, point-of-care tool for rheumatologists and we believe the proposed reduction for 76881 may reduce access to this diagnostic test while also increasing the use of more expensive advanced imaging like magnetic resonance imaging (MRI). We are particularly concerned that proposed changes to codes will not be subject to the phase-in of RVU reductions due to the significant shift of resource costs between codes in the same family. We have received feedback from our membership that many rheumatologists are using dedicated rooms and picture archiving and communication systems (PACs), which were some of the key items removed from the code. We respectfully request the opportunity to work with CMS to provide greater detail about the use of MSUS among rheumatology practices.

At minimum, we request that CMS reconsider this cut and use the phase-in approach of significant RVU reductions or delay the reduced code reimbursement for two reasons. First, within CMS's current framework, codes that are sufficiently similar are subject to phase-in whereby one-half of significant reduction would be applied over a two-year period. Second, a delay or phase-in will allow for time to work with CMS and other specialty societies to find a solution that would address our concerns. We also urge CMS to explore how these additional proposed decreases may have the unintended consequence of biasing the venue of care toward hospital based imaging centers.

The ACR understands these services fluctuate due to the growing number of Medicare beneficiaries with complex chronic conditions; however, we recommend that CMS reconsider the magnitude of the proposed decreases to code 76881 and employ a delay or phased-in approach.

Low Volume Codes

Any coding error or mistake with low volume codes can cause major payment differences in Medicare. To determine which codes are low volume for the coming year, CMS is proposing to use the expected specialty that CMS identifies on a list developed based on the most recent RUC recommendations. CMS proposes to consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis, which is in line with the recommendation of the RUC. The ACR agrees with the RUC recommendations to monitor these codes on an annual basis through the regular RUC process. The RUC is charged with reviewing the claims data for work, practice expense and professional liability insurance (PLI), which is done with the help of specialty society input. We believe

this process should be finalized in this way and we encourage CMS to continue working with the RUC and specialty societies through this methodology.

Overall Payment Update and Misvalued Code Targets

For CY 2018 the proposed overall update to payments under the PFS would be +0.31 percent. We understand this update reflects the +0.50 percent update established under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, reduced by 0.19 percent, due to the misvalued code target recapture amount, required under the Achieving a Better Life Experience (ABLE) Act of 2014. The ACR suggests that CMS use the 0.50% updates in MACRA to reflect the inflationary costs borne as overhead by providers who participate in the Medicare system.

Payment Rates for Non-excepted Off-campus Provider-Based Hospital Departments Paid Under the PFS

For CY 2018, CMS is proposing to reduce current PFS payment rates for these items and services by 50 percent. The proposal would change the PFS payment rates for these services from 50 percent of the OPPS payment rate to 25 percent of the OPPS rate. We ask for clarification regarding how CMS will handle 340b reimbursement with off-campus provider based hospital departments.

Medicare Telehealth Services

For CY 2018, CMS is proposing to add several codes to the list of telehealth services. The ACR views telehealth services as one part of a multidisciplinary solution to the projected workforce shortage in rheumatology. According to a 2015 ACR study, the current demand for rheumatologists is 5,615 FTE, 36 percent more than the available supply. By 2030, excess demand will be 4,729 or 138 percent more than supplyⁱ. We applaud CMS for adding additional codes to the list. CMS is further proposing to eliminate the required reporting of the telehealth modifier for professional claims in an effort to reduce administrative burden for practitioners. The ACR believes that allowing payment and reducing administrative burdens for coding would allow providers and patients to engage in furnish high-quality services and possibly improve access to medical care. We also encourage CMS to reimburse for the CPT codes that are bundled or non-paid for remote monitoring.

Malpractice Relative Value Units (RVUs)

We agree with the CMS proposal for malpractice RVUs to be developed using the most recent data available. The ACR applauds CMS for working on an area that consistently increases risk to the provider. We are open to working with CMS and other specialty societies on the topic of the physician payment component. We believe continuous transparency is needed across the board to make sure that any updates do not create any unintended consequences. The ACR also suggests CMS carry out extensive analysis with current data providers to ascertain existing data sources that could be helpful.

Care Management Services

The ACR praises CMS for seeking to reduce the burden on reporting chronic care management (CCM) services. We suggest allowing more providers to furnish these services for each patient, because particularly complex patients who would benefit from CCM services also benefit from seeing multiple providers.

Evaluation and Management (E/M) Services

The ACR applauds CMS for recognizing and agreeing with continued feedback from stakeholders that evaluation and management codes are potentially outdated and may need to be revised. While the history of present illness (HPI) and exam are important components in the evaluation and management of patients, we believe they should not be key drivers for the overall coding determination. We believe the proposed focus on the HPI and the physical exam is not enough to address the growing complexity and requirements for any level of E/M visits. Simplifying the requirements for E/M coding can be summed up in adopting the 1995 guidelines especially for cognitive specialties that work with a single organ.

Despite the knowledge and acknowledgement of inherent issues within the definition and valuation of E/M services, there has been no adjustment in the definitions and only incremental changes in their valuations since the development of the Resource-Based Relative Value Scale (RBRVS). This is despite the vastly expanded therapeutic and diagnostic choices, the increasingly complex interactions among treatments and concurrent conditions, and the conversation requirements of an increasingly health literate public. The work of cognitive specialists has evolved since these codes were created and the current E/M definitions do not fully capture the work of a growing population with chronic conditions.

We believe the current system of counting bullets to reach a recommended E/M level is outdated and does not focus on reaching the highest level of quality of care for any individual patient. There are too many discrepancies between auditors and payers on their methodology. There are also significant inconsistencies between the contractors on the E/M guidelines. We believe the coding concepts are ambiguous, which leaves too much room for interpretation based on individual auditors. The ACR is not opposed to accurate documentation of a patient's visit, but we are concerned that the push to make this a key component to determine the validity of an E/M level is inappropriate and fails to recognize the expertise and training of providers.

Further, clinical documentation represents the patient's clinical status and we recognize the need for legible, timely, complete, precise, and clear documentation. However, it appears that the need for improvement in documentation is driven by payment and not quality patient care. Patient care is not a one-size-fits-all and in the management of chronic care, providers spend ample time making the most appropriate therapeutic strategy for each patient. The focus on medical decision making for the cognitive specialist is the key to quality patient care as patients are receiving drug therapies that could be potentially toxic and require intensive drug monitoring to assure appropriate therapeutic levels. The ACR

along with other members of the Cognitive Care Alliance (CCA) believe in order for reformed documentation expectations for E/M services to have their fully intended effect, they must be linked to correcting the deficiencies in both definition and valuation of these services. The members of the Alliance are united in their belief that CMS cannot afford to continue to delay a thorough re-examination of the E/M codes.

Additionally, the ACR firmly believes that physicians are best suited to decide what components of a history and physical exam are required for each individual patient. Complexity of an office visit often includes cognitive services that may not be documented by a larger number of history or exam components, but rather a more complex decision-making process. There is currently no recognition of the clinical expertise achieved with years of training and experience that creates the ability to instantly recognize a pattern and make a diagnosis of enormous clinical value in a matter of moments. Therefore, the ACR suggests reducing the necessary aspects of history and physical exam features and instead allowing physicians to document complexity in the components of the assessment and plan. The ACR also suggests further study of E/M service codes to ensure that cognitive services are appropriately valued. We welcome the opportunity to work with CMS to achieve one of our long-standing goals to reexamine the E/M codes that have not been updated during the last quarter century.

Part B Drugs: Payment for Biosimilar Biological Products

In the CY 2016 PFS final rule with comment period, CMS finalized a proposal to make clear that average sales price (ASP) for all national drug codes (biosimilar products) assigned to the same reference biological product would be included in the same billing and payment code. This means that biosimilar products that rely on a common reference product's biologics license application are grouped into the same payment calculation for determining a single average sales price payment limit, and that a single Healthcare Common Procedure Coding System (HCPCS) code is used for such biosimilar products.

The ACR reiterates its support for assigning a unique J-code to each biosimilar of a particular reference product, so that physicians can better track and monitor their effectiveness and ensure adequate pharmacovigilance in the area of biosimilars. We encourage CMS to ensure drugs are not identified based on cost, as this may be the case with single J-codes. Drugs need to be distinguishable for billing units, measuring utilization and performance easily and accurately. We believe having a single J-code leaves room for flawed data.

CMS is soliciting comments on the effects of its payment policy based on experience with the United States' biosimilar product marketplace since the regulations went into effect on January 1, 2016; however, this policy has not taken effect because there is not yet more than one biosimilar for one originator biologic available through the Medicare Part B payment system. The ACR's internal analysis predicts that although Medicare's Part B reimbursement for provider-administered biosimilars will incentivize providers to choose lower-cost biosimilars by grouping all biosimilars for a single reference product into one reimbursement code, uptake will be reduced for those providers who are unable to offer a biosimilar because its cost is above the average price. This would likely be true of the large

plurality of rheumatologists who work in small groups, and we believe would disproportionately reduce access to biosimilars in rural and underserved areas.

New Care Coordination Services and Payment for Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs)

CMS is proposing that RHCs and FQHCs would receive payment for regular and complex chronic care management services, general behavioral health integration services, and psychiatric collaborative care model services using two new billing codes created exclusively for RHC and FQHC payment. It appears that this proposal will increase payment to clinics that serve traditionally underserved patients. If this is the case, the ACR is supportive of CMS's intention to improve access to critical services, which many Americans may not be receiving.

Appropriate Use Criteria for Advanced Diagnostic Imaging

The ACR applauds the proposed delay in implementing (AUC) for diagnostic imaging studies. We support simplifying and phasing-in the program requirements. The ACR also strongly supports larger exemptions to the program – for example, for physicians in small groups and rural and underserved areas. These changes would maximize patients' access to critical diagnostic testing. The ACR believes that small, rural, and independent practices are not ready for AUC implementation. Adding AUC features to electronic health records (EHRs) will be costly, and using them will take additional time away from patient care. We urge CMS to ask specialty organizations for input about specific AUC methods and until input is requested, provided, and integrated, the proposed start date should continue to be delayed.

Physician Quality Reporting System (PQRS)

We applaud CMS for incorporating stakeholder feedback and proposing to change the current PQRS program policy that requires reporting of nine measures across three National Quality Strategy domains to require reporting of six measures for the PQRS. We are also encouraged to see CMS also proposing similar changes to the clinical reporting requirements under the Medicare Electronic Health Record Incentive Program for eligible professionals.

Patient Relationship Codes

We applaud the CMS proposal that clinicians beginning January 1, 2018 may voluntarily report the HCPCS modifiers. Because CMS anticipates that there will be a learning curve with respect to the use of these modifiers, we agree they should be voluntary for their initial use.

Value Modifier (VM)

We are particularly pleased to see that CMS recognizes the need to revise the value modifier (VM), as this program imposes a significant regulatory burden. The proposed

changes would ease the automatic payment adjustment from -4 percent to -2 percent for groups of 10 or more clinicians who do not meet minimum quality reporting requirements; and from -2 percent to -1 percent for solo practitioners and groups of 2-9 clinicians. While the reductions in penalties represent a move in the right direction, the ACR recommends that CMS establish a VM adjustment of zero (0) for 2018. This would align with the agency's policy to "zero out" the impact of the Resource Use component of the Merit Based Incentive Payment System (MIPS) in 2019, the successor to the VM program. This provides additional time to continue refining the cost measures and gives physicians more time to understand the program.

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,

A handwritten signature in black ink, appearing to read "Sharad Lakhanpal". The signature is fluid and cursive, with the first name "Sharad" and last name "Lakhanpal" clearly distinguishable.

Sharad Lakhanpal, MBBS, MD
President, American College of Rheumatology

ⁱ Battaifarano D, Monrad S, Ditmyer M, Imundo L, Klein-Gitelman M. 2015 ACR/ARHP Workforce Study in the United States: Pediatric Rheumatologist Supply and Demand Projections for 2015-2030 [abstract]. Arthritis Rheumatol. 2016; 68 (suppl 10). <http://acrabstracts.org/abstract/2015-acrarhp-workforce-study-in-the-united-states-pediatric-rheumatologist-supply-and-demand-projections-for-2015-2030/>.