



January 16, 2018

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

Re: (CMS-4182-P) Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Program, and the PACE Program

Dear Administrator Verma:

The American College of Rheumatology (ACR), representing over 9,500 rheumatologists and health professionals, appreciates the opportunity to provide input on the *Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Program, and the PACE Program* proposed rule. Rheumatologists provide care for millions of Americans, both adults and children, and are the experts in diagnosing, managing and treating arthritis and rheumatic disease. These conditions include rheumatoid arthritis, systemic lupus erythematosus, and vasculitis. Rheumatologic diseases including arthritis are the leading cause of disability in the country, and early and appropriate treatment by a rheumatologist is vital to controlling disease activity, preventing and slowing progression, improving patient outcomes, and reducing the need for costly downstream procedures and care. Rheumatologists practice in every state and the District of Columbia, in communities small and large, providing critical care for people with diseases that can be crippling, life-changing and life-threatening. Because of the nature of rheumatologic diseases, which impact the elderly at a disproportionate rate, many patients seen by rheumatologists are Medicare beneficiaries.

Overview

The ACR is pleased to see the inclusion of several proposals that would improve care access and affordability for Medicare patients living with rheumatic diseases. Specifically, we applaud CMS for exploring mechanisms to encourage lower drug costs through greater pricing transparency on the part of pharmacy benefit managers in areas including rebates and pharmacy price concessions at point of sale. We are also encouraged that CMS is taking steps to update guidance regarding discriminatory cost-sharing practices. Further, we applaud CMS for proposing to revise the definition of generic drugs to include follow-on biological products, solely for purposes of cost sharing. Lower cost alternatives can improve enrollee incentives to choose follow-on biological products over more expensive reference biological products, and can reduce costs to both Part D and Medicare Advantage. However, we have concerns regarding provider burden, patient access, and enforcement of nondiscrimination in new benefit designs. Please find our comments below.

Proposed Policy Changes to Medicare Advantage and the Prescription Drug Benefit Program

Treatment of Follow-On Biological Products as Generics for Low Income Subsidy (LIS) Cost Sharing and Non-LIS Catastrophic Cost Sharing

The ACR applauds CMS' proposal to classify follow-on biological products as generics for the purposes of cost sharing for Part D enrollees who do not receive the LIS and are in the catastrophic portion of the benefit, and for LIS Part D enrollees throughout all phases of the benefit. Because of the current cost-sharing structure, beneficiaries in the "donut hole" have an incentive to purchase brand-name drugs over generics because they will pay less for them. Further, the way in which this structure steers patients toward biologic originators may reduce the market uptake for biosimilars, potentially raising drug prices and increasing costs for Medicare. We have actively advocated for this biosimilars "fix". We strongly encourage CMS to classify biosimilars as generics for these purposes, as this proposal will reduce out-of-pocket costs for people taking biosimilars. As a caveat, the ACR suggests that CMS make clear that biosimilars remain different from generics as a scientific and regulatory matter.

Ensure Additional Transparency for Star Ratings

CMS is proposing to codify key aspects of the Part C and D Star Ratings methodology, including the principles for adding, updating, and retiring measures, and the methodology for calculating and weighting measures. The ACR strongly discourages use of Beers criteria for punitive measures or quality ratings for individual providers and prescription drug plans. Prescription drug plans have taken steps that ultimately limit access to Beers criteria medications and have adverse consequences on practicing providers. We urge CMS to consider how using quality measures that would reduce star ratings of plans allowing of Beer's list medicines would curtail the autonomy of patients and physicians to use those medicines – such as NSAIDs and muscle relaxants to reduce pain and improve physical function on an individual basis – even when utilizing appropriate safety monitoring and when other medications such as opioids may be less preferable for individual patients.

ACR has been informed that drug plans are currently:

1. Contacting providers (usually by facsimile) about individual prescriptions on the Beers list of medications for beneficiaries over age 65
2. Restricting formulary coverage of Beers criteria medications for all beneficiaries over 65 and often for those who are not 65 but who receive part D Medicare benefits (i.e., SSI disability)
3. Imposing prior authorization constraints for these medications
4. Assigning low quality ratings to providers who prescribe Beers criteria medications

By taking these steps, drug plans "supersede clinical judgment or an individual patient's values and needs," in contradiction to the stated goals of the AGS 2012 Beers Criteria updateⁱ. They prevent individualized treatment and shared decision-making that the AGS values. Specifically, this prevents senior citizens from having access to arthritis treatments that are clinically indicated for relieving pain on an individual basis. It also punishes providers trying to provide appropriate care. The Beers criteria were never intended to be used by payors to limit access.

Artificial Limits on Medicare Advantage Plan Variety

The ACR supports CMS's proposal to eliminate the requirement that MA plans offered by the same

organization in the same county comply with artificial limits, for the purpose of increasing options for maintaining continuous insurance coverage for people with arthritis and rheumatic diseases. It is important that new flexibilities in benefit design help beneficiaries, caregivers, and family members make more informed plan choices, decrease premiums, and increase access to coverage. We encourage CMS to consider how the agency will ensure these potential savings will be passed on to beneficiaries in the form of lower premiums, while also maintaining coverage of essential and appropriate benefits.

Flexibility in the Medicare Advantage Uniformity Requirements

CMS' proposals regarding uniformity requirements will allow Medicare Advantage Organizations to offer disease-tailored benefit designs that include reduced cost sharing and deductibles for certain covered benefits. We are pleased to see that CMS made clear the benefit design must not be discriminatory for higher-cost enrollees. It is important to note that although disease-specific benefit designs may improve care for people who have certain healthcare needs, we have significant concerns regarding how the agency intends to enforce requirements related to nondiscrimination. We hope CMS will address this in the upcoming call letter addressing the operational details of this policy. The ACR continues to advocate for policies that promote more affordable out-of-pocket costs, which help to improve patients' adherence to treatment plans for arthritis and rheumatic diseases, preventing disability and shortened lifespan.

Maximum Out-of-Pocket and Cost Sharing Limits

Regarding the agency's proposals related to maximum out of pocket cost (MOOP), we urge CMS to consider to what extent changes to plan MOOP limits will affect beneficiaries with different healthcare costs. We caution against any changes that may have higher patient spending on A and B services, potentially causing disruptions in patient care.

The ACR supports and encourages CMS to develop, issue, and continue to update guidance regarding discriminatory cost sharing. The ACR strongly opposes excessive patient cost sharing that results in untenable patient financial burden. For patients with complex conditions like rheumatoid arthritis, biologic medications are very expensive and excessive cost sharing can reduce adherence and patient access to treatment.

Default Enrollment

CMS is seeking comment on whether to allow default enrollments in other circumstances beyond Medicare managed care. The ACR cautions against default enrollment for anyone outside of Medicaid managed care, and opposes such policy in the commercial market.

Passive Enrollment Opportunities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries

CMS is proposing to allow passive enrollment for full-benefit dually eligible beneficiaries from a non-renewing integrated D-SNP to another comparable plan. We believe passive enrollment might improve care coordination for some duals, but at the same time, it could reduce choice for select beneficiaries. Though CMS states this process would be conducted in consultation with a state Medicaid agency, it is important to note that there are areas, such as Washington DC, where parity between Medicaid and Medicare does not exist. This often results in barriers to dual eligible beneficiaries accessing biologic

medicines because of the lack of meaningful payment by Medicaid in the supplemental payments. To that end, in these areas providers' financial viability would be threatened if they were to offer Part B medicines.

Part D Tiering Exceptions

CMS is proposing to revise existing policy related to tiering exceptions, including the permissible limitations Part D plan sponsors may apply to tiering exception requests. By establishing a framework based on the type of drug (brand, generic, biological product) requested and the cost sharing of applicable alternative drugs, we have concerns that this may result in more paperwork for clinicians. We encourage CMS to consider ways to ensure the administrative burden will not increase for providers due to this policy.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

The ACR supports policies that would provide earlier access to generic drugs for beneficiaries taking brand drugs with newly approved generics as long as the savings are passed along to patients. We also ask CMS to consider how these changes to notice requirements may cause concern or confusion for some beneficiaries at the point of sale.

Manufacturer Rebates and Pharmacy Price Concessions to Point of Sale

The current lack of pass-through of price concessions increases costs for Medicare and beneficiaries alike. Therefore, the ACR fully supports maximal reduction of patient OOP costs by passing rebates and other price concessions to the patient. We are a member of the Alliance for Transparent and Affordable Prescriptions (ATAP), which notes that, while a pass-through policy would increase premiums, the increase is more than offset by the deep reductions in cost sharing at every level of pass-through. The potential savings for beneficiaries are significant: CMS notes with a 100% pass-through, beneficiaries would save \$56.9 billion overall or \$88.13 per month. The ACR, along with ATAP, supports a 100% pass-through, as it provides the biggest savings for beneficiaries and could prevent any gaming that might occur with a partial pass-through.

CMS appropriately highlights that there has been flexibility in how price concessions are categorized: some plans treat them as direct and indirect remuneration (DIR), while others take a different approach. Treating price concessions as DIR creates a premium advantage, which, as CMS notes, may result in plan sponsors sometimes choosing higher negotiated prices in exchange for higher DIR or even preferring a higher net cost drug over a lower-cost option. This practice is unacceptable. We believe there should be contract standards and definitional agreement for money flowing into PBMs. The ACR, along with ATAP partners, believe that definitional agreement and consistency are the foundation to most other policy solutions. Therefore we urge CMS to create a common definition of "rebate," "discount," "fee," and any other terms a PBM may use, whether the agency moves forward with a pass-through or not.

Reducing Unnecessary Paperwork Burden: Medical Loss Ratio

CMS is proposing to significantly reduce the amount of medical loss ratio (MLR) data that MA organizations and Part D sponsors submit to CMS on an annual basis. While we believe reducing administrative burden is important, we ask CMS to consider how this proposal could lead to any misuse by plan sponsors.

In conclusion, the ACR is dedicated to ensuring that patients with arthritis and rheumatic disease have access to continuous high-value and high-quality care. We appreciate the work that CMS does and the opportunity to respond to the *Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Program, and the PACE Program* proposed rule. We look forward to being a resource to you and to working with the agency as this rule is finalized. 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 "David I. Daikh". The signature is fluid and cursive, with the first name "David" being the most prominent part.

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

ⁱ The American Geriatrics Society 2012 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *Journal of the American Geriatrics Society*. 60(4):616-31, 2012 Apr.