



January 25, 2018

Assistant Secretary for Planning and Evaluation
Room 415F
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted via email CompetitionRFI@hhs.gov

Re: Department of Health and Human Services: Promoting Healthcare Choice and Competition Across the United States

Dear Ladies and Gentlemen:

The American College of Rheumatology (ACR) represents over 9,500 rheumatologists and rheumatology health professionals. Rheumatologists provide ongoing care for over 50 million Americans with complex chronic and acute conditions that require specialized expertise. We appreciate the opportunity to provide input on the *Department of Health and Human Services (HHS) Request for Information on Promoting Health Care Choice and Competition Across the United States*. 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 (RA), systemic lupus erythematosus, and other debilitating diseases. Early and appropriate treatment by rheumatologists slows disease progression, improves patient outcomes, and reduces the need for costly downstream procedures and care that is complicated and made more expensive by advanced disease states and disability.

The ACR is dedicated to ensuring excellence in the care of both adults and children with autoimmune and musculoskeletal diseases. The ACR is deeply concerned about any barriers that may limit the ability of patients with arthritis or other rheumatic diseases to obtain affordable, high quality, high value healthcare. The ACR therefore advocates for patient access to adequate and affordable health insurance, access to a rheumatologist for initial consultative services as well as ongoing care, and patient access to treatments for rheumatic conditions. We are pleased to offer our views about state and federal laws and regulation that we believe create barriers to choice across the United States.

State or Federal laws, regulations, or policies that reduce or restrict competition and choice in healthcare markets

The ACR continues to be highly concerned about Medicare Part B drug payments being subject to the Merit-Based Incentive Payment System (MIPS) payment adjustments. We have urged the Centers for Medicare and Medicaid Services (CMS) and now Congress to exclude Part B medication costs from the MIPS payment adjustment. The ACR continues to advocate for a correction to this significant departure from longstanding CMS policy with regard to the application of quality program payment adjustments. Previous programs including PQRS, meaningful use, and the value-based modifier applied payment adjustments to physician services, but did not apply them to drugs. We reiterate our concern that, if MIPS adjustments are being made on very large amounts of money representing specialty drug costs,

for which by law providers are reimbursed ASP + approximately 4.2%, then MIPS adjustment would most likely reduce reimbursement by more than the ASP + 4.2 (i.e., it could be -5%; in future years, -9%) and the adjustment could quickly bankrupt a practice.

Further, we believe this policy could make it more difficult for physicians and other healthcare providers, particularly those in small practices and in rural settings, to administer Part B medications in their communities, creating a dire patient access issue. Many patients already face access to care challenges because the budget sequester has eroded reimbursements to physicians, and this policy would exacerbate these problems. Patients would have fewer options for where they could receive care, resulting in less access and higher costs. Many patients would then have to seek care in alternative settings that could result in higher out of pocket expenses and, particularly in rural communities, may require traveling a longer distance to receive care. We encourage CMS to work with Congress in order to rectify this dangerous policy and its unintended adverse consequences.

Additionally, the ACR supports reevaluation of the Stark law policies against physician self-referral in order to align new health care delivery models with value-based and shared risk reimbursement models. The “Stark” self-referral policies that were enacted nearly 30 years ago now pose barriers to care coordination. The Stark Law prohibits payment arrangements that consider the volume or value of referrals or other business generated by the parties. These prohibitions can stifle care delivery innovation by inhibiting practices from incentivizing their physicians to deliver patient care more effectively and efficiently, because the practices cannot use resources from designated health services in rewarding or penalizing adherence to clinical guidelines and treatment pathways.

We therefore support HHS having authority to waive the prohibitions in the Stark Law and associated fraud and abuse laws for physicians seeking to develop and operate Alternative Payment Models (APMs) as was provided to Accountable Care Organizations in the Affordable Care Act. We also recommend removing the “volume or value” prohibition in Stark policy so that physician practices can incentivize physicians to abide by best practices and succeed in the new value-based alternative payment models. This protection would apply to physician practices that are developing or operating an alternative payment model including, Advanced APMs, APMs approved by the Physician-Focused Payment Model Technical Advisory Committee, MIPS APMs, and other APMs specified by the Secretary.

State or Federal laws, regulations, or policies that may promote or encourage anticompetitive behavior in healthcare markets

The ACR has applauded CMS’ decision to revise its policy for reimbursing biosimilars under the Medicare Part B program as a part of the 2018 Physician Fee Schedule Final Rule. The agency has now begun to assign separate billing codes for biosimilars, instead of grouping all biosimilars from the same reference product into the same code. We reiterate our 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 not to reverse course and to continue to ensure drugs are not identified based on cost, as this may be the case with single J-codes. Drugs need to be separately distinguishable for billing units, measuring utilization and performance easily and accurately. Ultimately, we believe having a single J-code would leave room for flawed data.

At the state level, the ACR would recommend amending the McCarron-Ferguson Act. The McCarron-Ferguson Act (15 U.S.C. 1013) exempts insurance companies from federal antitrust laws. H.R. 372, which has passed the U.S. House of Representatives, would remove this protection except for the purposes of (1) collecting, compiling, or disseminating historical loss data; (2) determining a loss development factor for historical loss data; (3) performing actuarial services if the collaboration does not involve a restraint of trade; or (4) developing or disseminating a standard insurance policy form if adherence to the form is not required. This needed change gives the federal government the ability to intervene in places where insurance monopolies exist or develop. This would be especially helpful in areas where local insurance monopolies have developed from market consolidation and other factors since the passage of the Affordable Care Act (ACA), potentially increasing patient costs for insured care and treatments.

Policies or other solutions to promote the development and operation of a more competitive healthcare system that provides high-quality care at affordable prices for the American people

According to a 2016 AMA survey of 1,000 practicing physicians, a medical practice completes an average of 37 prior authorization (PA) requirements weekly per physician, taking a physician and their staff an average of 16 hours, or the equivalent of two business days, to process¹. We believe this is a waste of valuable resources that results in delays in care and does not add value to healthcare delivery. Several organizations representing physicians, hospitals, pharmacists, medical groups, and patients, including the ACR, have developed and endorsed 21 Prior Authorization and Utilization Management Reform Principles that are intended to serve as best practices and reasonable reforms for utilization management (UM) programs. The ACR urges all entities engaged in UM—including CMS—to follow these principles:

- CMS should require Part D plans to accept and respond to pharmacy PA and step therapy override requests through the NCPDP electronic PA transactions.
- CMS should accelerate automation of medical services PA by (a) issuing a rule for an electronic clinical attachment standard and (b) enforcing health plan compliance with the X12 278.
- CMS should ensure that all UM requirements are based on accurate and up-to-date, publicly available clinical criteria and never cost alone.
- CMS should require all MA and Part D plans to publicly disclose in a searchable electronic format to both patients and physicians all drugs and medical services that are subject to coverage restrictions (PA, step therapy, formulary restrictions, quantity limits), and provide this information to vendors to be displayed in electronic health record systems.
- CMS should require a 60-day grace period for UM requirements when a patient changes MA and Part D plans, should align PA approvals with the duration of the prescribed/ordered treatment, and should prohibit plans from requiring patients to retry therapies failed under previous plans.
- MA and Part D plans should abide by PA decisions and pay for any services approved in a PA request by performing eligibility and all other medical policy coverage determinations as part of

the PA process and not revoking or restricting coverage for authorized care provided within 45 business days from the date the authorization was received.

- Except where there is evidence of widespread misuse, PA should not be required for drugs that are standard treatment for the patient's condition and/or have been previously approved for treatment of an ongoing/chronic condition.
- CMS should ensure that any "peer-to-peer" reviews utilize physicians from the same specialty/subspecialty as the ordering physician.
- CMS should restrict PA requirements to "outlier" providers whose prescribing or ordering patterns differ significantly from their peers after adjusting for patient mix.
- CMS should not allow Part B services to be subject to PA requirements, because this would increase physician time spent on administrative tasks and reduce availability for patient care.

Additionally, the ACR has concerns regarding the practices of pharmacy benefit managers (PBMs). The PBM industry is overly consolidated with the two largest PBMs covering more than 170 million Americans. This consolidation results in one-sided formulary negotiations with pharmaceutical manufacturers and an unfaltering demand by the PBMs, at the cost of the patient. As the intermediary hired by insurers to manage drug benefit programs, PBMs were originally created to control drug costs by negotiating discounts on the behalf of patients. However, PBMs have become increasingly effective at keeping much of the savings for themselves by often pocketing the difference between the fees they charge to pharmacies and the prices they negotiate from manufacturers – prices that exist behind a steel curtain. These practices drive up co-pays and out-of-pocket costs for patients while providing record profits to PBMs.

We urge HHS to consider policies that require PBMs to be more transparent about their payment practices, including transparency around the true cost of prescription drugs. The system would also benefit from policies requiring more uniformity or standardization in the ways that PMBs structure and convey their rebate programs, including uniform definitions for terms used in disclosures by specifying what constitutes a rebate, discount, fee, and amount received from a manufacturer. The current lack of uniformity can obscure how money flows through the system and can lead to unfair competition and ultimately additional financial burden for patients. As we mentioned in our comments to CMS 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, the ACR fully supports maximal reduction of patient OOP costs by passing rebates and other price concessions to the patient.

While this RFI does not include request for comment on certain proposed rules including the Notice of Benefit and Payment Parameters and the Association Health Plan proposed rule, we would reiterate our concerns around association health plans (AHPs), short-term, limited-duration insurance (STLDI), and flexibilities around essential health benefits (EHBs). The ACR recommends that all Americans be covered by continuous health insurance that encourages high quality health care including care for chronic arthritis and rheumatic diseases, and that minimizes interruptions in treatment. Any new proposals for health care should include protections for Americans with pre-existing conditions, requiring essential

health benefits that include services particularly valuable to arthritis patients, and making plans with affordable premiums, low deductibles and minimal cost sharing available. While AHPs, STLDIs, and flexibility for states with regard to EHBs may lower insurance premiums for some, we are concerned that essential health benefits that are vital to individuals living with rheumatic disease – such as rehabilitation, prescription medicines, and lab testing – could be reduced or restricted.

Additionally, eliminating the cost sharing reduction (CSR) measures may reduce low-income patients' access to health insurance, thus making it difficult for them to access the care they require. Rheumatic diseases are life-long, chronic conditions that require continuous health insurance coverage that encourages high quality care. The ACR plans to provide further comment on the Department of Labor Association Health Plan proposed rule in the upcoming months.

In conclusion, laws, policies, and regulations should allow providers to focus on medical decision-making, the prioritization of care, and careful resource allocation, resulting in an improved, more efficient healthcare system. We appreciate HHS creating the opportunity to provide public feedback on the *Department of Health and Human Services (HHS) Request for Information on Promoting Health Care Choice and Competition Across the United States*. If you require any additional information, please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs, at kamodeo@rheumatology.org or (202) 210-1797.

Sincerely,



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

ⁱ <https://www.ama-assn.org/sites/default/files/media-browser/public/government/advocacy/2016-pa-survey-results.pdf>